

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

STATE OF FLORIDA,

Plaintiff,

v.

Case No. 8:21-cv-839

XAVIER BECERRA, Secretary of
Health and Human Services, in his
official capacity; HEALTH AND
HUMAN SERVICES; ROCHELLE
WALENSKY, Director of the
Centers for Disease Control and
Prevention, in her official capacity;
CENTERS FOR DISEASE
CONTROL AND PREVENTION;
The UNITED STATES OF
AMERICA,

Defendants.

_____ /

**COMPLAINT FOR DECLARATORY AND
PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF**

INTRODUCTION

1. The COVID-19 pandemic caused massive disruption and harm across the world. As of April 7, 2021, there have been 30,596,830 reported cases and 554,420 deaths in the United States.¹

2. Those numbers, which are staggering and sobering, do not portray the full picture. The pandemic started with great uncertainty and caused great fear. But with resolve, purpose, and ingenuity, we have developed multiple vaccines, therapeutics, and treatments that have reduced the mortality at unparalleled speed.

3. As of April 6, 2021, 32.6% of the U.S. population has received at least one vaccine dose, while 19% is fully vaccinated.² Importantly, 75.9% of those 65-and-older have received at least one dose,³ as states like Florida have prioritized the vaccination of vulnerable groups like seniors.

4. The country is returning to normal. Florida is leading the way and has remained more open than many other large states. Industries have adapted to COVID-19 in Florida and are adapting elsewhere. They have found ways to do business safely, and before long, most Americans will be vaccinated.

¹ <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

² <https://covid.cdc.gov/covid-data-tracker/#vaccinations>.

³ <https://covid.cdc.gov/covid-data-tracker/#vaccinations>.

5. On April 6, 2021, President Biden announced that all adults will be eligible to receive a vaccine by April 19, and he has set as a goal beginning to return to normal by the July 4th holiday.⁴ Florida is ahead of President Biden's goal, both with reopening and with vaccinations. As of April 5, all adults in Florida are eligible for a vaccine.

6. Despite the virus, and those who would lock down society indefinitely, people are traveling again. They are doing so safely with protective measures like vaccines, sanitation, and social distancing. On April 5, for example, 1,561,959 individuals traveled on airplane flights in the United States—almost fifteen times the number who were flying on the same day a year earlier.⁵ It is not just air travel. Hotels, theme parks, restaurants, and many other industries are safely reopening.

7. But as these industries begin to restart and rebuild, the cruise industry has been singled out, and unlike the rest of America, prevented from reopening. Despite the demonstrated success of reasonable COVID-19 safety protocols in Europe and Asia, the cruise industry in the United States has been subject to a nationwide lockdown since March 2020. As a result, the industry is on the brink of financial ruin.

⁴ <https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/11/remarks-by-president-biden-on-the-anniversary-of-the-covid-19-shutdown/>.

⁵ <https://www.tsa.gov/coronavirus/passenger-throughput>.

8. In October 2020, the Centers for Disease Control and Prevention (“CDC”) expressly found that continuing this nationwide lockdown was unjustifiable. But since that time, notwithstanding its public decision to allow the cruise industry to reopen, the CDC has functionally continued the lockdown. And it now appears the CDC will continue that lockdown until November 2021, even though vaccines are now available to all adults who want them.

9. The CDC does not have the authority to issue year-and-a-half-long nationwide lockdowns of entire industries. And even if it did, its actions here are arbitrary and capricious and otherwise violate the Administrative Procedure Act (“APA”).

10. Florida asks this Court to set aside the CDC’s unlawful actions and hold that cruises should be allowed to operate with reasonable safety protocols.

11. Absent this Court’s intervention, Florida will lose hundreds of millions of dollars, if not billions. And, more importantly, the approximately 159,000 hard-working Floridians whose livelihoods depend on the cruise industry could lose everything.

PARTIES

12. Plaintiff State of Florida is a sovereign State and has the authority and responsibility to protect the wellbeing of its public fisc and the health, safety, and welfare of its citizens.

13. Defendants are the United States, appointed officials of the United States government, and United States governmental agencies responsible for the issuance and implementation of the challenged administrative actions.

14. Florida sues Defendant the United States of America under 5 U.S.C. §§ 702–03 and 28 U.S.C. § 1346.

15. Defendant CDC issued and is implementing the October 30, 2020 Order, establishing its Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew (the “Conditional Sailing Order”). *See* Ex. 1. The CDC is a component of Defendant the Department of Health & Human Services (“HHS”).

16. Defendant Rochelle Walensky is the Director of the CDC. She is sued in her official capacity.

17. Defendant Xavier Becerra is the Secretary of HHS. He is sued in his official capacity.

JURISDICTION AND VENUE

18. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1346, and 1361 and 5 U.S.C. §§ 702–03.

19. The Court is authorized to award the requested declaratory and injunctive relief under 5 U.S.C. § 706, 28 U.S.C. § 1361, and 28 U.S.C. §§ 2201–02.

20. Venue lies in this district pursuant to 28 U.S.C. § 1391(e)(1) because the State of Florida is a resident of this judicial district. Venue lies in this district under that provision for the independent reason that a substantial part of the events or omissions giving rise to the claim occurred in this judicial district—Tampa Bay is a major cruise port.

FACTUAL BACKGROUND

Florida's Cruise Industry

21. The cruise industry is an essential part of Florida's economy. In 2019, the industry's direct expenditures in Florida generated "nearly 159,000 total jobs paying \$8.1 billion in income."⁶

22. Of all cruise embarkations in the United States, approximately 60% embark from Florida.⁷ In 2019, approximately 11 million cruise passengers and crew members came ashore in Florida. These visitors spend money in Florida's local economies, and many Florida businesses depend on them.

The COVID-19 Pandemic

23. Beginning in early 2020, the COVID-19 pandemic devastated the cruise industry, like it did many industries. Outbreaks aboard cruise ships

⁶ <https://cruising.org/-/media/research-updates/research/2019-usa-cruise-eis.ashx>, at 11, 43.

⁷ <https://cruising.org/-/media/research-updates/research/2019-usa-cruise-eis.ashx>, at 6, 9, 15, 42.

were a significant concern, and experts, public officials, and medical personnel had a limited understanding of the virus, how to treat it, and how to prevent its transmission.

24. In March 2020, many cruise ships in the U.S. voluntarily ceased operations. Around that same time, on March 14, 2020, the CDC began issuing nationwide lockdown orders applicable to the cruise industry, just as many states issued lockdown orders against their citizens. *See Ex. 2.*

25. The CDC renewed its March 14 Order on April 9, July 16, and September 30. *See Ex. 3; Ex. 4; Ex. 5.*

26. The cruise industry has been “ravaged,” with “companies reporting billions of dollars in losses, causing some of them to downsize their fleets and sell ships for scrap.”⁸

The October 30 Conditional Sailing Order

27. On October 30, 2020, the CDC offered the cruise industry a glimmer of hope. Just as airlines, bus lines, hotels, restaurants, universities, theme parks, casinos, bars, and countless other industries have learned lessons during the pandemic and figured out how to operate safely—usually with precautions and reduced capacity—the CDC indicated that the cruise industry could do the same.

⁸ <https://www.nytimes.com/2021/03/19/travel/coronavirus-cruises.html>.

28. In its Conditional Sailing Order, the CDC purported to lift its lockdown order. It found that the “benefits of” opening “outweigh the costs of not allowing cruise ships to sail” so long as “cruise ships have taken the necessary precautions to mitigate risk.” Ex. 1 at 16. But, as explained below, the Order has been “nothing more than an extension of a cruise ban wrapped as a present.”⁹

29. The Order begins by incorporating the findings of the earlier lockdown orders, and it expressly relies on what occurred on cruise ships at the beginning of the pandemic when the entire world was struggling to control the spread of COVID-19. Ex. 1 at 8, 12. It also expressly bases its conclusions on the lack of an available “FDA . . . authorized vaccine.” *Id.* at 8.

30. The Order then praises the cruise industry for taking “steps to improve their public health response to COVID-19.” *Id.* at 13.

31. Next, the Order discusses the CDC’s “Request for Information,” which appears to be the CDC’s attempt to solicit feedback from the public without formally committing to notice and comment. *Id.* at 14.

32. The Order then discusses the alternatives it considered. It appears to have considered only two: (1) outright free rein for cruise ships with no

⁹ <https://www.cruisehive.com/signs-that-cruises-could-start-in-june-from-the-u-s/47910>.

oversight and no COVID-19 safety protocols whatsoever, and (2) continuing its lockdowns. *Id.* at 15–16.

33. After discussing these alternatives, the Order explains its “plan” for reopening. This involves four phases: (1) “establishment of laboratory testing of crew onboard cruise ships in U.S. waters,” (2) “simulated voyages designed to test a cruise ship operator’s ability to mitigate COVID-19 on cruise ships,” (3) “a certification process,” and (4) “a return to passenger voyages in a manner that mitigates the risk of COVID-19.” *Id.* at 16–17.

34. Unlike the previous orders, which were of limited time duration and had to be renewed, the Conditional Sailing Order is effective for a year, until November 1, 2021. *Id.* at 41. In other words, unless cruise ship companies can complete the four-phase process, they will be shut down until November 1, 2021.

35. Much has changed since October 30, 2020.

36. *First*, multiple FDA-approved vaccines are now available, and most of the U.S. population will likely be vaccinated by summer. *See* ¶¶ 3, 5. Moreover, the effectiveness of the FDA-approved COVID-19 vaccines dwarfs the effectiveness of, for example, the average influenza vaccine. This

explains why, on March 8, 2021, the CDC released a statement that fully vaccinated people could, in its view, begin resuming certain activities.¹⁰

37. *Second*, the cruise industry is “stirring to life” abroad.¹¹ European and Asian cruises, for example, are reopening with “resounding success.”¹² Indeed, “[t]here have already been some success stories out of Europe where cruise lines have shown that they’ve got great protocols in place, that they are committed to adhering to them, that they can keep passengers in a bubble and that they can do effective testing.”¹³

38. *Third*, other industries—such as airlines, bus lines, hotels, restaurants, universities, theme parks, casinos, and bars—have continued to reopen successfully with reasonable COVID-19 protocols.

39. As all of these changes were rendering the burdensome four-phase reopening process obsolete, the CDC made little progress. Over five months in, no cruise company has begun phase-two test voyages.

40. At a March 18, 2021 Senate hearing, Senator Lisa Murkowski of Alaska asked Defendant CDC Director Walensky to “give . . . some indicator in

¹⁰ <https://www.cdc.gov/media/releases/2021/p0308-vaccinated-guidelines.html>.

¹¹ <https://www.nytimes.com/2021/03/19/travel/coronavirus-cruises.html>.

¹² <https://www.cruisehive.com/signs-that-cruises-could-start-in-june-from-the-u-s/47910>.

¹³ <https://www.nytimes.com/2021/03/19/travel/coronavirus-cruises.html>.

terms of a timeline” for phase two. Ex. 6 at 7. Defendant Walensky responded, “I can’t.” *Id.*

41. At this rate, it is likely the industry will be locked down until at least November. While the CDC issued new guidance on April 2, 2021, this guidance is only a portion of what the industry needs before it can start phase-two test voyages.¹⁴ And this new guidance doesn’t adequately account for the CDC’s recent statement that “fully vaccinated people can travel at low risk to themselves.”¹⁵ Moreover, the guidance moves the goal posts yet again. For example, the CDC has increased the reporting frequency of COVID-19-like illnesses by cruise ship operators from weekly to daily. It also now requires cruise ship operators to enter into agreements with all U.S. port and local health authorities where they intend to dock.

42. The CDC has continued these actions against the cruise industry even as it has treated similar industries differently, including ones that hold passengers in close quarters. For example, the CDC has not shut down the airline industry—focusing instead on “cleaning of aircraft” and “recommendations for hand hygiene.”¹⁶

¹⁴ <https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html>; <https://www.cdc.gov/quarantine/cruise/instructions-local-agreements.html>.

¹⁵ <https://www.cdc.gov/media/releases/2021/p0402-travel-guidance-vaccinated-people.html>.

¹⁶ <https://www.cdc.gov/quarantine/air/managing-sick-travelers/ncov-airlines.html>.

Florida's Irreparable Harm

43. As a result of Defendants' actions, Florida has suffered hundreds of millions of dollars in harm, perhaps more. During the pandemic, Florida's ports have suffered a decline in operating revenue of almost \$300 million, and this figure is projected to increase to nearly \$420 million by July 2021.

44. In 2019, before Defendants shut down the cruise industry, Florida received approximately \$102.8 million in tax revenue from embarkations.

45. And even the above numbers do not fully account for the economic impact on Florida of Defendants' actions. For example, since March 1, 2020, at least 6,464 former cruise industry employees have filed for state Reemployment Assistance benefits. Florida has paid them approximately \$20 million in state benefits. And Florida receives other taxes as a direct or indirect result of the cruise industry, such as employment taxes and ground transportation taxes.

46. Finally, if the U.S. cruise industry does not reopen soon, cruise lines are considering relocating abroad. They may never come back.

47. Florida now seeks relief from this Court to prevent the irreparable harm Defendants' actions are causing.

CLAIMS

COUNT 1

Agency action not in accordance with law and in excess of authority

(Violation of the APA)

48. Florida repeats and incorporates by reference ¶¶ 1–47.

49. Under the APA, a court must “hold unlawful and set aside agency action” that is “not in accordance with law” or “in excess of statutory . . . authority, or limitations, or short of statutory right.” *See* 5 U.S.C. § 706(2)(A), (C).

50. The Conditional Sailing Order purports to derive its statutory and regulatory authority from 42 U.S.C. § 264 and 42 C.F.R. § 70.2 (the regulation implementing Section 264).¹⁷ Ex. 1 at 2, 20.

51. The Order is in excess of that authority in several ways.

52. *First*, neither 42 U.S.C. § 264 nor 42 C.F.R. § 70.2 authorizes the CDC to make or enforce regulations that suspend the operation of cruise ships, much less every cruise ship in the country. Such a reading of those provisions would be “tantamount to creating a general federal police power.” *Skyworks, Ltd. v. CDC*, 2021 WL 911720, at *10 (N.D. Ohio 2021).

¹⁷ Any other authorities the CDC has relied on are related to these two authorities, and fail to justify the CDC’s actions for the same reasons discussed below. *See, e.g.*, 42 U.S.C. § 268; 42 C.F.R. § 71.31(b).

53. *Second*, Sections 264 and 70.2 permit the CDC to act only if it first “determines that the measures taken by” a state “are insufficient to prevent the spread” of a communicable disease “from such State . . . to any other State.” 42 C.F.R. § 70.2. But here, the CDC has made no valid determination that the measures taken by Florida to protect the health and safety of its residents and tourists are insufficient. And any such determination would have to first take into account that people are now traveling with protective measures like vaccines, sanitation, and social distancing, and that the cruise industry has safely and successfully resumed sailing outside of U.S. waters.

54. *Third*, the CDC’s reading of its authority under 42 U.S.C. § 264 is wrong because it is divorced from context. The statute gives the CDC the authority to “make and enforce such regulations as in [its] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.” 42 U.S.C. § 264(a). But in the next sentence, the statute clarifies that to “carry[] out and enforc[e]” those regulations, it authorizes the CDC to conduct “such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in [CDC’s] judgment may be necessary.” *Id.* This second sentence clarifies the narrow nature of this

authority. *See, e.g., Paroline v. United States*, 572 U.S. 434, 447 (2014) (discussing catch-all terms that “bring[] within a statute categories similar in type to those specifically enumerated”); Antonin Scalia & Bryan Garner, *Reading Law: The Interpretation of Legal Texts* 199 (2012) (“Where general words follow an enumeration of two or more things, they apply only to persons or things of the same general kind or class specifically mentioned (*ejusdem generis*).”); *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988) (“In ascertaining the plain meaning of [a] statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole.”). In other words, the “second sentence . . . lists illustrative examples of the types of actions the CDC may take,” and those examples limit the scope of the CDC’s authority. *Skyworks*, 2021 WL 911720, at *9 (so holding); *accord Tiger Lily, LLC v. Dep’t of Hous. & Urb. Dev.*, 2021 WL 1165170 (6th Cir. 2021) (“Plainly, government intrusion on property to sanitize and dispose of infected matter is different in nature from a moratorium on evictions.”).

COUNT 2

Arbitrary and capricious agency action

(Violation of the APA)

55. Florida repeats and incorporates by reference ¶¶ 1–47.

56. Under the APA, a court must “hold unlawful and set aside agency action” that is “arbitrary [or] capricious,” as Defendants’ actions are here. 5 U.S.C. § 706(2)(A).

57. *First*, Defendants ignored important aspects of the problem. *See Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also Michigan v. EPA*, 576 U.S. 743, 751–53, 759–60 (2015). The lack of an FDA-approved vaccine in October 2020 was central to Defendants’ decision to impose a burdensome framework on the cruise industry, yet Defendants did not consider the fact that vaccines would be available long before the Order expires in November 2021. And they have made inadequate efforts to consider the significant developments on that front since. Moreover, Defendants have made no effort to account for the success of foreign cruise companies, which operate safely with reasonable COVID-19 protocols. Instead, Defendants rely on stale information from the beginning of the pandemic before industries and public-health officials learned how businesses could operate safely.

58. *Second*, Defendants’ reasoning is inadequate. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). “The agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” *Id.* In addition to the issues discussed in the preceding paragraph, the

Conditional Sailing Order states that it is necessary because “measures taken by State and local health authorities regarding COVID-19 onboard cruise ships are inadequate,” but the Order does not identify the measures taken by States and localities and the cruise industry itself, much less explain how the measures are inadequate. *See* Ex. 1 at 19.

59. *Third*, Defendants failed to consider lesser alternatives, *see DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009), such as imposing reasonable COVID-19 protocols, which have proved successful abroad.

60. *Fourth*, Defendants failed to explain their differential treatment of the cruise industry versus other industries. It is “textbook administration law that an agency must provide a reasoned explanation for . . . treating similar situations differently.” *W. Deptford Energy, LLC v. FERC*, 766 F.3d 10, 20 (D.C. Cir. 2014) (cleaned up). “[A]n agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so.” *Kreis v. Sec’y of Air Force*, 406 F.3d 684, 687 (D.C. Cir. 2005).

61. *Fifth*, Defendants have acted in an arbitrary and capricious manner by failing to meaningfully follow their own Conditional Sailing Order. The Order provides that cruise lines will have an opportunity to complete a four-phase framework and “return to passenger operations,” *see* Ex. 1 at 16–17, but the CDC has neither provided cruise lines an opportunity

to complete the framework nor allowed any cruise line to return to passenger operations, notwithstanding that the “benefits of” opening “outweigh the costs of not allowing cruise ships to sail,” Ex. 1 at 16.

COUNT 3

Agency Action Unlawfully Withheld or Unreasonably Delayed

(Violation of the APA)

62. Florida repeats and incorporates by reference ¶¶ 1–47, 57–61.

63. In the alternative, and for the same reasons stated in Count 2, Defendants’ failure to allow the cruise industry to safely reopen constitutes final agency action unlawfully withheld or unreasonably delayed, in violation of 5 U.S.C. § 706.

COUNT 4

Failure to Provide Notice and Comment

(Violation of the APA)

64. Florida repeats and incorporates by reference ¶¶ 1–47.

65. The APA required Defendants to provide notice of, and receive comment on, the Conditional Sailing Order because it is a substantive rule that “affect[s] individual rights and obligations.” *Chrysler Corp. v. Brown*, 441 U.S. 281, 303 (1979); *see* 5 U.S.C. § 553.

66. Defendants, however, failed to conduct proper notice and comment rulemaking. As a perennial excuse, Defendants seem to rely on the “good

cause” exception to the notice requirement, *see* 5 U.S.C. § 553(b)(B), and lean heavily on the year-old “emergency” of COVID-19. *See, e.g.*, Ex. 1 at 19, 20. But that exception “is to be narrowly construed and only reluctantly countenanced.” *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012).

67. Good cause to depart from notice and comment does not exist when the agency has sufficient time to provide notice and comment. *See Kollett v. Harris*, 619 F.2d 134, 145 (1st Cir. 1980); *Regeneron Pharm., Inc. v. Dep’t of Health & Hum. Servs.*, 2020 WL 7778037, at *11 (S.D.N.Y. Dec. 30, 2020) (noting that an agency’s contemplation of rulemaking for two years “suggests that the agency could have acted sooner and complied with the notice and comment requirements”). So even if the good cause exception were applicable in March 2020, it no longer applies in April 2021.

68. Moreover, even if an emergency could still be said to exist one year later such that it justifies “good cause,” this exception to notice and comment is supposed to be temporary. *See Am. Fed’n of Gov’t Emp., AFL-CIO v. Block*, 655 F.2d 1153, 1158 (D.C. Cir. 1981).

69. And although the CDC solicited information from the public, the CDC did not respond or even attempt to address in any meaningful way the comments provided to it. Ex. 1 at 14–15. This suggests the CDC did not view that process as satisfying the notice and comment requirements, and even if it did, its failure to respond is fatal. *See Perez v. Mortg. Bankers Ass’n*, 575 U.S.

92, 96 (2015) (explaining that “[a]n agency must consider and respond to significant comments received during the period for public comment”).

COUNT 5

Unconstitutional Exercise of Legislative Power

(Violation of U.S. Const. Art. I, § 1)

70. Florida repeats and incorporates by reference ¶¶ 1–47.

71. Article I, Section 1 of the U.S. Constitution states, “[a]ll legislative powers herein granted shall be vested in a Congress of the United States.” Under Article I, Section 1, only Congress may engage in lawmaking.

72. If the Conditional Sailing Order does not exceed the authority under 42 U.S.C. § 264 and the relevant regulations, then Section 264 constitutes an unconstitutional exercise of lawmaking by the executive branch, affording the CDC the power to determine the rights of millions of citizens, to decide on the survival of countless businesses, and to make a host of sweeping policy decisions absent meaningful accountability.

PRAYER FOR RELIEF

For these reasons, Florida asks the Court to:

- a) Hold unlawful and set aside the Conditional Sailing Order.
- b) Issue preliminary and permanent injunctive relief enjoining Defendants from enforcing the Conditional Sailing Order.
- c) Postpone the effective date of the Conditional Sailing Order.

- d) Declare unlawful the Conditional Sailing Order.
- e) Declare that the cruise industry may open with reasonable safety protocols.
- f) Award Florida costs and reasonable attorney's fees.
- g) Award such other relief as the Court deems equitable and just.

Respectfully submitted,

Ashley Moody
ATTORNEY GENERAL

John Guard (FBN 374600)
CHIEF DEPUTY ATTORNEY GENERAL

/s/ James H. Percival
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Counsel for the State of Florida

JS 44 (Rev. 10/20)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

<p>I. (a) PLAINTIFFS</p> <p style="text-align: center;">STATE OF FLORIDA</p> <p>(b) County of Residence of First Listed Plaintiff <u>All counties, including</u> <i>(EXCEPT IN U.S. PLAINTIFF CASES)</i></p> <p>(c) Attorneys <i>(Firm Name, Address, and Telephone Number)</i></p> <p style="text-align: center;">See attachment.</p>	<p>DEFENDANTS</p> <p>Xavier Becerra, Secretary of Health and Human Services, in his official capacity; et al.</p> <p>County of Residence of First Listed Defendant _____ <i>(IN U.S. PLAINTIFF CASES ONLY)</i></p> <p>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.</p> <p>Attorneys <i>(If Known)</i></p>
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<p>II. BASIS OF JURISDICTION <i>(Place an "X" in One Box Only)</i></p> <p><input type="checkbox"/> 1 U.S. Government Plaintiff</p> <p><input checked="" type="checkbox"/> 2 U.S. Government Defendant</p> <p><input type="checkbox"/> 3 Federal Question <i>(U.S. Government Not a Party)</i></p> <p><input type="checkbox"/> 4 Diversity <i>(Indicate Citizenship of Parties in Item III)</i></p>	<p>III. CITIZENSHIP OF PRINCIPAL PARTIES <i>(Place an "X" in One Box for Plaintiff and One Box for Defendant)</i></p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width:30%;"></td> <td style="width:10%; text-align: center;">PTF</td> <td style="width:10%; text-align: center;">DEF</td> <td style="width:40%;"></td> <td style="width:10%; text-align: center;">PTF</td> <td style="width:10%; text-align: center;">DEF</td> </tr> <tr> <td>Citizen of This State</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td>Incorporated or Principal Place of Business In This State</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business In Another State</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> </tr> </table>		PTF	DEF		PTF	DEF	Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input type="checkbox"/> 5	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
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IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<p>PERSONAL INJURY</p> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <p>PERSONAL PROPERTY</p> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <p>PROPERTY RIGHTS</p> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016 <p>SOCIAL SECURITY</p> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))
<p>REAL PROPERTY</p> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<p>CIVIL RIGHTS</p> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	<p>PRISONER PETITIONS</p> <p>Habeas Corpus:</p> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <p>Other:</p> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act <p>IMMIGRATION</p> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit (15 USC 1681 or 1692) <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input checked="" type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

1 Original Proceeding 2 Removed from State Court 3 Remanded from Appellate Court 4 Reinstated or Reopened 5 Transferred from Another District *(specify)* 6 Multidistrict Litigation - Transfer 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity):*
 5 U.S.C. § 706; 5 U.S.C. § 553

Brief description of cause:
 Challenge under the Administrative Procedure Act and U.S. Constitution

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. **DEMAND \$** _____ CHECK YES only if demanded in complaint:
JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY *(See instructions):*

JUDGE _____ DOCKET NUMBER _____

DATE 4/7/2021 SIGNATURE OF ATTORNEY OF RECORD [Signature]

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
 Original Proceedings. (1) Cases which originate in the United States district courts.
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
 Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

CIVIL COVER SHEET ATTACHMENT

I. (c) Attorneys (Firm Name, Addresses, and Telephone Number)

John Guard (FBN 374600)
CHIEF DEPUTY ATTORNEY GENERAL

James H. Percival (FBN 1016188)
CHIEF DEPUTY SOLICITOR GENERAL

Jason H. Hilborn (FBN 1008829)
ASSISTANT SOLICITOR GENERAL

Anita Patel (FBN 70214)
SENIOR ASSISTANT ATTORNEY GENERAL

Office of the Attorney General
The Capitol, P1-01
Tallahassee, Florida 32399-1050
(850) 414-3300
(850) 410-2672 (fax)
james.percival@myfloridalegal.com

Counsel for the State of Florida

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____.

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____, and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____, who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____; or

I returned the summons unexecuted because _____; or

Other *(specify)*:

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 _____.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

Civil Action No. _____

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_____ on *(date)* _____; or

I returned the summons unexecuted because _____; or

Other *(specify)*:

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I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Florida

STATE OF FLORIDA

Plaintiff(s)

v.

XAVIER BECERRA, Secretary of Health and Human Services, in his official capacity, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) United States of America
c/o United States Attorney's Office
Civil Process Clerk
Middle District of Florida
400 N. Tampa St., Suite 3200
Tampa, FL 33602

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

State of Florida
Ashley Moody, Florida Attorney General
James H. Percival, Chief Deputy Solicitor General
Office of the Attorney General
The Capitol, PL-01, Tallahassee, Florida 32399-1050
james.percival@myfloridalegal.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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I personally served the summons on the individual at *(place)* _____
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I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
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I returned the summons unexecuted because _____ ; or

Other *(specify)*:

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 _____ .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

EXHIBIT 1

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)**

**ORDER UNDER SECTIONS 361 & 365
OF THE PUBLIC HEALTH SERVICE ACT (42 U.S.C. 264, 268) AND
42 CODE OF FEDERAL REGULATIONS
PART 70 (INTERSTATE) AND PART 71 (FOREIGN):**

**FRAMEWORK FOR CONDITIONAL SAILING AND
INITIAL PHASE COVID-19 TESTING REQUIREMENTS
FOR PROTECTION OF CREW**

Executive Summary

The Centers for Disease Control and Prevention (CDC), a component of the U.S. Department of Health and Human Services (HHS), announces this framework for a phased resumption of cruise ship passenger operations. Considering the continued spread of COVID-19 worldwide and increased risk of COVID-19 on cruise ships, a careful approach is needed to safely resume cruise ship passenger operations. CDC is establishing requirements to mitigate the COVID-19 risk to passengers and crew, prevent the further spread of COVID-19 from cruise ships into U.S. communities, and protect public health and safety. After expiration of CDC's No Sail Order (NSO) on October 31, 2020, CDC will take a phased approach to resuming cruise ship passenger operations in U.S. waters.

The initial phases will consist of testing and additional safeguards for crew members. CDC will ensure cruise ship operators have adequate health and safety protections for crew

members while these cruise ship operators build the laboratory capacity needed to test future passengers. Subsequent phases will include simulated voyages to test cruise ship operators' ability to mitigate COVID-19 risk, certification for ships that meet specific requirements, and a phased return to cruise ship passenger voyages in a manner that mitigates COVID-19 risk among passengers, crew members, and U.S. communities. These phases are subject to change based on public health considerations and cruise ship operators' demonstrated ability to mitigate COVID-19 risk. CDC will issue additional orders as needed that will be published in the Federal Register and technical instructions that will be subsequently posted on CDC's website.

This Order additionally announces requirements for the initial phases relating to crew testing. CDC considers adequate crew safeguards as demonstrated through laboratory testing for SARS coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, an integral part of the initial phases prior to resuming passenger operations.

Previous Orders and Incorporation by Reference

The findings and other evidence relied upon in issuing the No Sail Order and Other Measures Related to Operations signed by the CDC Director on March 14, 2020,¹ as further

¹ No Sail Order and Suspension of Further Embarkation.
<https://www.federalregister.gov/documents/2020/03/24/2020-06166/no-sail-order-and-suspension-of-further-embarkation>. Last accessed October 19, 2020.

modified and extended effective April 15, 2020,² July 16, 2020,³ and September 30, 2020⁴—are incorporated herein by reference.

Statement of Intent

This Order shall be interpreted and implemented in a manner as to achieve the following paramount objectives:

- Preserving human life;
- Preserving the health and safety of cruise ship crew members, port personnel, and communities;
- Preventing the further introduction, transmission, and spread of COVID-19 into and throughout the United States;
- Preserving the public health and other critical resources of Federal, State, and local governments;
- Preserving hospital, healthcare, and emergency response resources within the United States; and
- Maintaining the safety of shipping and harbor conditions.

Acronyms, Initialisms, and Definitions

² No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations. <https://www.federalregister.gov/documents/2020/04/15/2020-07930/no-sail-order-and-suspension-of-further-embarkation-notice-of-modification-and-extension-and-other>. Last accessed October 19, 2020.

³ No Sail Order and Suspension of Further Embarkation, Second Modification and Extension of No Sail Order and Other Measures Related to Operations. <https://www.federalregister.gov/documents/2020/07/21/2020-15810/no-sail-order-and-suspension-of-further-embarkation-second-modification-and-extension-of-no-sail>. Last accessed October 19, 2020.

⁴ No Sail Order and Suspension of Further Embarkation; Third Modification and Extension of No Sail Order and Other Measures Related to Operations. <https://www.federalregister.gov/documents/2020/10/05/2020-22030/no-sail-order-and-suspension-of-further-embarkation-third-modification-and-extension-of-no-sail>. Last accessed October 19, 2020.

(a): The acronyms and initialisms below will have the following meaning:

aCLI means additional COVID-like illness signs and symptoms as defined by the Council of State and Territorial Epidemiologists (CSTE) and that are not included in the definitions of ARI, ILI, or pneumonia, or as defined by CDC in technical instructions. CDC will use the most current CSTE definition in effect, which may be found at:

<https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/>

ARI means Acute Respiratory Illness defined as the presence of cough, sore throat, or runny nose (rhinorrhea) in the absence of fever and in the absence of a non-infectious diagnosis (e.g., allergies) as determined by the ship's medical provider, or as defined by CDC in technical instructions.

CLI means COVID-like Illness.

CDC means U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, or an authorized representative acting on its behalf.

EDC means Enhanced Data Collection.

ILI means influenza-like illness defined as fever (≥ 100.4 °F [38 °C]) plus either cough or sore throat or as defined by CDC in technical instructions.

USCG means United States Coast Guard, Department of Homeland Security.

(b): The terms below will have the following meaning:

Controlled Free Pratique has the same meaning as under 42 C.F.R. § 71.1.

COVID-19 means the disease caused by the coronavirus SARS-CoV-2.

COVID-like Illness means ARI, ILI, pneumonia, aCLI, or other signs or symptoms of COVID-like illness as defined by CDC in technical instructions.

Crew or Crew member means any individual serving on board a cruise ship who is assigned to perform regular duties or tasks on behalf of a cruise ship operator in exchange for compensation.

Cruise ship means any commercial, non-cargo, passenger-carrying vessel operating in U.S. waters with the capacity to carry 250 or more individuals (passengers and crew) with an itinerary anticipating an overnight stay onboard or a twenty-four (24) hour stay onboard for either passengers or crew.⁵

Cruise ship operator means the master of the vessel (cruise ship) and any other crew member responsible for cruise ship operations and navigation, as well as any person or entity (including a corporate entity) that authorizes or directs the use of a cruise ship (e.g., as owner, lessee, or otherwise). A cruise ship operator may also include the cruise ship captain or the cruise line to which the cruise ship belongs, and the officers and directors of the cruise line.

Director means the Director of the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, or an authorized representative.

Isolation means measures taken by a cruise ship operator to ensure the onboard or onshore separation of passengers or crew displaying signs or symptoms of COVID-19, or who have tested positive SARS-CoV-2, from other passengers or crew who do not display such signs or symptoms or have not tested positive for SARS-CoV-2.

Laboratory Testing or Laboratory Test Results means testing performed in a laboratory certified as meeting the standards of the Clinical Laboratory Improvement Amendments (CLIA)

⁵ Cruise ships are defined in the same manner as in CDC's No Sail Orders, as extended and modified, that were issued between March 14 and September 30, 2020. CDC continues to define cruise ships in this manner based on substantial epidemiologic evidence related to congregate settings and mass gatherings. While evidence shows that outbreaks can occur in small settings such as nursing homes, as the numbers of passengers and crew on board a ship increase, certain recommended mitigation efforts such as social distancing become more difficult to implement. Considering the demonstrated rapid spread of COVID-19, the application of this framework to cruise ships carrying 250 or more passengers and crew remains prudent and warranted.

of 1988 (42 U.S.C. 263a) and 42 CFR 493 or CLIA-waived point-of-care testing or the results of such testing. Testing must be performed using tests that are approved, cleared, or authorized for emergency use by the U.S. Food and Drug Administration (FDA) as specified by CDC in technical instructions or orders.

Operate or Operating in U.S. waters means any action by a cruise ship operator to bring or cause a cruise ship to be brought into or transit in or between any waterways (e.g., shifting berths, moving to anchor, discharging waste, making port, or embarking or disembarking passengers or crew) subject to the jurisdiction of the United States.

Passenger means any individual being transported or offered transport on board a cruise ship who is not a crew member, excluding U.S. government personnel.

Passenger operations means any action by a cruise ship operator to cause passengers to embark or disembark a cruise ship.

Person means any individual or partnership, firm, company, corporation, association, organization, or other legal entity.

Quarantine means measures taken by a cruise ship operator to ensure the onboard or onshore separation and restriction of movement of passengers or crew who were potentially exposed to a person with COVID-19 while that person was considered infectious.

Responsible officials means the Chief Executive Officer (or equivalent) of the operating cruise company and all parent companies, the Chief Compliance Officer (or equivalent) of the operating cruise company and all parent companies, and the highest-ranking Medical Officer of the operating cruise company and all parent companies.

Simulated voyage means a mock voyage or series of mock voyages designed and implemented in so far as possible to replicate real world onboard conditions of cruising with measures in place to mitigate the risk of COVID-19.

Social distancing means maintaining a distance of at least 6 feet between one individual and another individual, not gathering in groups, and avoiding crowded places and mass gatherings.

U.S. waters means any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States.

Background and Need to Establish a Framework for Mitigating the Risk of COVID-19 Onboard Cruise Ships Prior to Resuming Passenger Operations

The coronavirus disease 2019 (COVID-19) pandemic continues to spread rapidly around the world with no U.S. Food and Drug Administration (FDA) authorized vaccine. As of October 30, 2020, a cumulative total of over 44 million cases and nearly 1.2 million confirmed deaths have now been reported worldwide. Even in countries that have managed to slow the rate of transmission, the risks for COVID-19 resurgence remains. In the United States, as of October 29, 2020, there have been over 8.8 million cases and over 227,000 confirmed deaths. Based on the evidence gathered and explained in the No Sail Order issued on March 14, as modified and extended on April 15, July 16, and September 30, 2020, there is ample reason to believe that absent mitigation measures of the type needed to prevent further transmission, cruise ship travel has the potential to exacerbate and amplify the spread of SARS coronavirus 2 (SARS-CoV-2) the virus that causes COVID-19.

Unrestricted cruise ship travel would likely exacerbate and amplify the spread of SARS coronavirus 2 (SARS-CoV-2) the virus that causes COVID-19. On January 20, 2020, the *Diamond Princess* cruise ship departed Yokohama, Japan. On January 25, 2020, a symptomatic passenger departed the ship in Hong Kong, where he was later confirmed to have COVID-19. Upon the ship's return to Yokohama, Japanese authorities quarantined all passengers and crew

on board the ship. Among the 3,711 *Diamond Princess* passengers and crew, 712 (19.2%) were subsequently confirmed to have COVID-19, 37 required intensive care, and nine died. Following this outbreak, two voyages of the *Grand Princess* cruise ship were ultimately associated with 159 confirmed COVID-19 cases, including eight deaths.⁶

Because of these events, and the increased risk of transmission on cruise ships, on March 14, 2020, the CDC Director issued a *No Sail Order and Other Measures Related to Operations* directing cruise ships not voluntarily suspending operations to comply with certain measures (85 FR 16628). This followed a March 13, 2020, announcement by Cruise Line International Association (CLIA), the leading industry trade group, that its members would voluntarily suspend cruise ship operations. On March 17, 2020, CDC issued a Level 3 Travel Health Notice warning all travelers to defer cruise travel worldwide based on widespread ongoing transmission of COVID-19.⁷ Despite the announcement by CLIA, the application of the March 14, 2020 Order, and the Level 3 Travel Health Notice, cruise ships continued to be associated with new COVID-19 outbreaks. Between March 14 and April 15, 2020, COVID-19 outbreaks were reported on several additional cruise ships with passengers (85 FR 21004).

Accordingly, to protect public health and safety and prevent the further introduction, transmission, and spread of COVID-19 into and throughout the United States, the CDC Director issued *No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations*, modifying and extending the previous March 14, 2020 Order, which became effective on April 15, 2020 (85 FR 21004). Under the

⁶ Moriarty LF, Plucinski MM, Marston BJ, et al. Public Health Responses to COVID-19 Outbreaks on Cruise Ships — Worldwide, February–March 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:347-352. <https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e3.htm>. Last accessed June 25, 2020.

⁷ CDC Travel Health Notice, *COVID-19 and Cruise Ship Travel*, at: <https://wwwnc.cdc.gov/travel/notices/warning/coronavirus-cruise-ship> (originally posted, March 17, 2020). Last accessed June 25, 2020.

April 15, 2020 Extension, as a condition of obtaining controlled free pratique⁸ to continue to engage in cruise ship operations in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, cruise ship operations were limited, and cruise lines were required to submit plans to prevent, mitigate, and respond to the spread of COVID-19 on board to ensure a safe work environment and disembarkation for crew members. A cruise ship operator's No Sail Order response plan had to minimize to the greatest extent possible any impact on U.S. Government operations or the operations of any State or local government, or the U.S. healthcare system. While working with cruise ship operators to ensure the completeness and accuracy of these response plans, CDC allowed crew members to disembark from cruise ships in U.S. waters and return home if cruise ship operators formally attested, in writing, to complying with requirements to disembark crew members in such a manner as to minimize the risk to other travelers and communities.

Following the April 15, 2020 Extension, CDC published its *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew* to assist cruise ship operators in preventing, detecting, and medically managing confirmed and suspected SARS-CoV-2 infections and exposures among crew members.⁹ During this period, CDC also further assisted cruise ship operators with humanitarian medical evacuations for people in need of lifesaving support. Under the April 15, 2020 Extension, CDC established an enhanced surveillance process to provide a more complete picture of COVID-19 activity on cruise ships through a requirement for weekly submission of the "Enhanced Data Collection (EDC) During COVID-19 Pandemic Form (OMB Control Number 0920-0134, exp. 03/31/2022)". Since then, the EDC form has been used to

⁸ Under 42 C.F.R. § 71.1, controlled free pratique means permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.

⁹ CDC, *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew* at: <https://www.cdc.gov/quarantine/cruise/management/interim-guidance-no-sail-order.html>

conduct surveillance for COVID-19 among crew who remained on board cruise ships based on cumulative reports of acute respiratory illness (ARI),¹⁰ influenza-like illness (ILI),¹¹ pneumonia, and other clinical indicators of COVID-19 (85 FR 62732).

As of October 30, 2020, EDC reports have shown a total of 6,725 polymerase chain reaction (PCR) tests performed, 296 (4%) of which were positive; 24 hospitalizations; 2 instances of mechanical ventilation; and 15 medical evacuations for crew on ships within U.S. jurisdiction since April 15, 2020. CDC also recommended that ships' surveillance include routine testing for SARS-CoV-2 infection, including intermittent testing of a random sample of symptomatic and asymptomatic crew members.

In addition to reviewing the No Sail Order response plans, CDC continued to update its *Interim Guidance* as new information became available; provided technical expertise to ships with ongoing outbreaks; created cruise ship-specific websites to inform crew members, the public, and partners; and reviewed hundreds of written attestations submitted by cruise operators for safe disembarkation and transfer of crew members.

CDC established a "COVID-19 Color Coding System" for ships applicable to cruise ship operators with an appropriate No Sail Order response plan for crew management. Classification of ships under this system requires cruise company officials to sign an acknowledgment of the completeness and accuracy of their No Sail Order response plans upon completion of CDC review of the plan. CDC assesses the status of a ship by reviewing surveillance data from the weekly EDC form as well as recent embarkations or crew transfers. Additional details regarding the color-coding system and color coding status for individual ships (which is updated weekly)

¹⁰ Acute Respiratory Illness (ARI) is defined as the presence of cough, sore throat, or rhinorrhea in the absence of fever.

¹¹ Influenza-like Illness (ILI) is defined as fever (100.4 °F [38 °C]) plus either cough or sore throat.

may be found at <https://www.cdc.gov/coronavirus/2019-ncov/travelers/crew-disembarkations-commercial-travel.html>.

To continue to protect public health and safety, and prevent the further introduction, transmission, and spread of COVID-19 into and throughout the United States, the CDC Director signed a *Second Modification and Extension of No Sail Order and Other Measures Related to Operations* on July 16, 2020, (85 FR 44085), and *Third Modification and Extension of No Sail Order and Other Measures Related to Operations* on September 30, 2020, (85 FR 62732). This last order, among other things, continued to suspend passenger operations on board cruise ships through October 31, 2020.

Current scientific evidence suggests that, absent mitigation measures of the type needed to prevent further transmission, cruise ships would continue to pose a greater risk of COVID-19 transmission than other settings. A recent article published in the *Journal of Travel Medicine* by Rocklöv et al. demonstrated that the *Diamond Princess* cruise ship experienced an onboard R_0 (basic reproduction rate) for COVID-19 of 14.8 before ship-wide quarantine was enacted.¹² This means that each case onboard the *Diamond Princess* transmitted COVID-19 to approximately 15 other people. This reproduction rate is approximately four times higher than the R_0 of the original epicenter of the outbreak in Wuhan, China, which was 3.7, meaning that each person with COVID-19 in the early days of the outbreak in Wuhan transmitted the disease to approximately four other people. In late February/early March, 149 cases of PCR-confirmed COVID-19 (of 589 tour participants) were found among U.S. residents linked to Egyptian Nile Cruises. This heightened rate of transmission onboard cruise ships has also been documented in

¹² Rocklöv J, Sjödin H, Wilder-Smith A. COVID-19 Outbreak on the Diamond Princess Cruise Ship: Estimating the Epidemic Potential and Effectiveness of Public Health Countermeasures. *J. Travel Med.* 2020; 18;27(3):taaa030. doi: 10.1093/jtm/taaa030.

other academic publications.^{1,13} Absent appropriate interventions to mitigate the spread of COVID-19, cruise ship conditions would likely amplify the spread of an already highly transmissible disease.

Rocklöv et al. surmised that this heightened rate of transmission is due to the high population density on board ships, which are typically more densely populated than cities or most other living situations. While this is one contributing factor, CDC's surveillance data collected through the EDC form and acquired during the period of the No Sail Order show that drastically decreasing population on board, absent other interventions, is not enough to extinguish transmission. Other factors likely contributing to onboard transmission are crews' living and working in close quarters, in a partially enclosed environment, and where social distancing may prove challenging even with a limited number of people onboard.

In addition, the recent investigation by Payne et al. of transmission onboard a U.S. Navy ship demonstrated high transmission rates and high rates of mild disease and asymptomatic infection among crew.⁸ These mild presentations and asymptomatic cases make case detection and isolation and quarantine practices based on clinical presentation alone challenging. Thus, covert spread of infection among crew may keep the virus circulating from one voyage to the next. This again stresses the need for appropriate interventions, including routine laboratory testing of crew, prior to restarting passenger operations.

Several cruise ship operators have taken steps to improve their public health response to COVID-19. For example, under the co-chairmanship of former Health and Human Services Secretary, Michael O. Leavitt, and former FDA Commissioner, Dr. Scott Gottlieb, two cruise lines, Royal Caribbean Group and Norwegian Cruise Line Holdings, assembled a "Healthy Sail

¹³ Payne DC, Smith-Jeffcoat SE, Nowak G, et al. SARS-CoV-2 Infections and Serologic Responses from a Sample of U.S. Navy Service Members — USS Theodore Roosevelt, April 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:714–721. DOI: <http://dx.doi.org/10.15585/mmwr.mm6923e4>.

Panel” of subject-matter experts from a variety of disciplines. The World Travel & Tourism Council (WTTC) and Carnival Corporation also recently hosted a global science summit on COVID-19 designed, “to inform practical, adaptable and science-based solutions for mitigating and living with COVID-19.” MSC Cruises further established its own industry-led panel with “competency to review policy initiatives, technical innovations, or operational measures related to COVID-19.”

To gather more information regarding industry-led efforts to respond to COVID-19 and solicit public input, on July 20, 2020, CDC published a Request for Information (RFI) in the Federal Register related to cruise ship planning and infrastructure, resumption of passenger operations, and additional summary questions (85 FR 44083). The document had a 60-day comment period that ended on September 21, 2020 and nearly 13,000 comments were received.

Respondents to the RFI included members of the public, the cruise industry, seaport authorities, and the travel and hospitality industries. A majority of respondents (approximately 75%) expressed support for the resumption of passenger cruising in the U.S. Most of these commenters, however, expressed the need for increased public health measures, including health screening, testing, mask use, social distancing, travel insurance, refunds, and shipboard public health capacity as important steps to take before cruising resumes. Approximately 25% of respondents, including many previous cruise passengers, were in favor of delaying the resumption of passenger cruising because of the current state of the pandemic, and supported waiting until a vaccine is widely available.

Comments received related to the reduction of number of passengers, the need for routine testing of passengers and crew, social distancing, coordination between CDC and the cruise industry, limiting ports of call to private islands, agreements with local public health and medical facilities, and the economic benefits of cruising. Approximately 98% of respondents supported

cruise ship operators denying boarding to passengers with COVID-like illness or confirmed COVID-19 infection, while approximately 65% of respondents supported denying boarding to passengers with known COVID-19 exposure in the previous 14 days before embarkation. A majority of respondents (74%) also supported requiring that cruise ship operators test passengers and crew prior to embarkation. Furthermore, approximately 90% of respondents supported cruise ship operators reducing passenger and crew loads to reduce the risk of COVID-19 transmission, while approximately 85% supported the wearing of face masks by passengers. While CDC bases its public health determinations on the best available science and not on public opinion, the willingness of the public to accept measures to mitigate the risk of transmitting COVID-19 onboard cruise ships is noteworthy. Accordingly, CDC carefully considered these comments in drafting this framework.

CDC also considered alternatives to this framework. One alternative considered was allowing cruise ship operators to return to unrestricted passenger operations without any public health oversight. This alternative was deemed unacceptable because cruise ship travel is known to contribute to COVID-19 transmission. Furthermore, mild presentations and asymptomatic cases make case detection and isolation and quarantine practices challenging absent robust testing. Thus, covert spread of infection among crew may keep the virus circulating from one voyage to the next and passengers infected on cruise ships could further spread COVID-19 into U.S. communities by traveling interstate after cruising. This would have the effect of increasing morbidity and mortality, and burdening federal, state, and local medical and public health infrastructure. This again stresses the need for appropriate public health oversight.

Public health oversight is further needed to correct a market failure stemming from information asymmetry, i.e., the public is often not fully informed in such a way to adequately determine the extent to which any given measure mitigates their personal risk, particularly in

light of asymptomatic cases. CDC is therefore overcoming this market failure by ensuring that the measures taken by cruise ship operators are those that are most likely to adequately mitigate such risks.

Another alternative considered was continuing to issue No Sail Orders as occurred between March 14 and September 30, 2020. However, this alternative was not found to be as optimal as the current framework. The benefits of this framework outweigh the costs of not allowing cruise ships to sail because it allows for flexibility where cruise ships have taken the necessary precautions to mitigate risk, while continuing to prohibit passenger operations onboard ships that have failed to implement such precautions. As such, the current framework represents a tailored approach that was determined to be preferable to the status quo No Sail Order. This framework allows for individual cruise lines to progress through phases at variable paces. This enables cruise lines successfully implementing public health measures to return to passenger operations more quickly while others by necessity may move more slowly. The framework not only encourages cruise lines that are more successful at mitigating the spread of COVID-19 but provides a realistic timeline that anticipates COVID-19 continuing to be present and affecting cruise ship travel.

While the actions taken by some cruise ship operators to improve their public health response to COVID-19 are encouraging, ongoing public health oversight is needed to ensure uniform standards for mitigating the communicable disease risk to crew and prospective passengers. The public health measures in this framework reflect CDC's considered views as to the minimum standards that must be in place prior to resuming passenger operations in a way that will mitigate the risk of COVID-19.

CDC intends to take a phased approach to resuming passenger operations. These phases include: (1) establishment of laboratory testing of crew onboard cruise ships in U.S. waters; (2)

simulated voyages designed to test a cruise ship operators' ability to mitigate COVID-19 on cruise ships; (3) a certification process; and (4) a return to passenger voyages in a manner that mitigates the risk of COVID-19 introduction, transmission, or spread among passengers and crew onboard ships and ashore to communities. These phases will be further determined based on public health considerations including the trajectory of COVID-19 transmission and the demonstrated ability of cruise ship operators to successfully employ measures that mitigate the risk of COVID-19.

As part of the initial crew testing phases, this Order additionally contains requirements for: (1) shoreside COVID-19 laboratory screening testing of all crew currently onboard; (2) onboard diagnostic testing capabilities for symptomatic travelers (crew and future passengers); (3) shoreside COVID-19 laboratory screening testing of all newly embarking crew; and (4) continued compliance by cruise ship operators with their complete, accurate, and acknowledged, No Sail Order Response Plans.

Findings and Immediate Action

The continued spread of the COVID-19 pandemic worldwide, risk of resurgence in countries that have suppressed transmission, and ongoing concerns related to the restart of cruising, supports the establishment of a framework designed to mitigate the risk of COVID-19 onboard cruise ships.

Accordingly, and consistent with 42 CFR §§ 70.2, 71.31(b), and 71.32(b), the Director of CDC ("Director") continues to find that absent measures of the type needed to mitigate further transmission, cruise ship travel exacerbates the global spread of COVID-19, that the scope of this pandemic is inherently and necessarily a problem that is international and interstate in nature, and such transmission has not been controlled sufficiently by the cruise ship industry or

individual State or local health authorities. As described in the March 14, 2020, Order, as further modified and extended on April 15, 2020, July 16, 2020, and September 30, 2020, cruise ship travel markedly increases the risk and impact of the COVID-19 disease epidemic within the United States. If unrestricted cruise ship passenger operations were permitted to resume, infected and exposed persons disembarking cruise ships would place federal partners (e.g., Customs and Border Protection and the U.S. Coast Guard), healthcare workers, port personnel, and communities at substantial unnecessary risk. Unrestricted cruise ship travel would also divert and overburden scarce federal, state, and local, public health and healthcare resources during a pandemic.

The Director also continues to find evidence to support a reasonable belief that cruise ships are or may be infected or contaminated with a quarantinable communicable disease.¹⁴ This reasonable belief is based on information from epidemiologic and other data included in this document and the information described in the March 14, 2020, Order and the April 15, July 16, and September 30 2020, modifications and extensions. As a result, absent measures of the type needed to mitigate further transmission, persons on board or seeking to board cruise ships may likely be or would likely become infected with or exposed to COVID-19 by virtue of being on board at a time when cases of COVID-19 continue to be reported in increasingly significant numbers globally.¹⁵ Additionally, persons infected on cruise ships would be likely to transmit COVID-19 to U.S. communities by traveling interstate after cruising.

¹⁴ COVID-19 is a communicable disease for which quarantine is authorized under Section 361 of the Public Health Service Act (42 U.S.C. § 264) and 42 CFR §§ 70.1, 71.1, as listed in Executive Order 13295, as amended by Executive Orders 13375 and 13674.

¹⁵ Since the March 14, 2020, Order, the number of global cases of COVID-19 reported by the World Health Organization (WHO) has risen from 142,534 to more than 44 million as of October 30, 2020, with nearly 1.2 million deaths. See Situation Reports, WHO, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports>.

Accordingly, under 42 CFR § 70.2, the Director determines that measures taken by State and local health authorities regarding COVID-19 onboard cruise ships are inadequate to prevent the further interstate spread of the disease. Cruise ships by their very nature travel interstate and internationally and can move beyond the jurisdictional boundaries of any single state or local health authority. Furthermore, local transmission of COVID-19 onboard a cruise ship can escalate quickly into additional interstate and international transmission when infected persons travel. Therefore, federal intervention is needed to require public health measures to prevent the further introduction, transmission, or spread of COVID-19 via cruise ships globally and into U.S. communities.

This Order is not a rule within the meaning of the Administrative Procedure Act (“APA”), but rather an emergency action taken under the existing authority of 42 CFR §§ 70.2, 71.31(b), and 71.32(b). CDC published a Request for Information (RFI) in the Federal Register that solicited and obtained public comment related to cruise ship planning and infrastructure, resumption of passenger operations, and additional summary questions (85 FR 44083). In the event that this Order qualifies as a rule under the APA, notice and comment and a delay in effective date are not required because CDC has already obtained public comment and good cause exists to dispense with prior public notice and the opportunity to further comment on this Order.¹⁶ Considering the public health emergency caused by COVID-19 based on, among other things, its potential for spread on board cruise ships, it would be impracticable and contrary to the public’s health, and by extension the public’s interest, to delay the issuance and effective date of this Order. Similarly, if this Order qualifies as a rule per the definition in the APA, the Office of Information and Regulatory Affairs has determined that it would be a major rule, but there

¹⁶ See 5 U.S.C. §§ 553(b)(B), (d)(3).

would not be a delay in its effective date as the agency has invoked the good cause provision of the APA.

If any provision in this Order, or the application of any provision to any carriers, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, persons, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

In accordance with 42 U.S.C. § 264(e), this Order shall supersede any provision under State law (including regulations and provisions established by political subdivisions of States), that conflict with an exercise of Federal authority, including instructions by U.S. Coast Guard or HHS/CDC personnel permitting ships to make port or disembark persons under stipulated conditions, under this Order.

This Order shall be enforceable through the provisions of 18 U.S.C. §§ 3559, 3571; 42 U.S.C. §§ 243, 268, 271; and 42 CFR §§ 70.18, 71.2.

Therefore, in accordance with Sections 361 and 365 of the Public Health Service Act (42 U.S.C. §§ 264, 268) and 42 CFR §§ 70.2, 71.31(b), 71.32(b), for all cruise ships described above for the period described below, it is **ORDERED**:

Framework for Conditional Sailing

Purpose and Scope.

(a) *Purpose.* The purpose of this framework is to prevent the further introduction, transmission, and spread of COVID-19 into and throughout the United States via cruise ships. These requirements are in addition to other requirements in regulations or actions taken by HHS/CDC to prevent the introduction, transmission, and spread of communicable diseases under 42 U.S.C. § 264 and 42 CFR part 70 and 42 CFR part 71.

(b) *Scope*. This framework applies to any person operating or intending to operate a cruise ship in U.S. waters and to any person operating a cruise ship outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in U.S. waters while this Order remains in effect.

(1) Upon request, cruise ship operators must make their properties and records available for inspection to allow CDC to ascertain compliance with this framework. Such properties and records include but are not limited to vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, and employee and passenger health records.

(2) CDC may enforce any of the provisions of this framework through additional orders published in the Federal Register and issue additional technical instructions as needed.

(3) Nothing in this framework supersedes or preempts enforcement of emergency response requirements imposed by statutes or other regulations.

(4) Cruise ship operators may use the services of professionally licensed and accredited third-party auditors to assist them in meeting the requirements of this framework.

Notwithstanding, the cruise ship operator's responsible officials maintain an overall duty and responsibility for meeting the requirements of this framework, including the requirements of any technical instructions or orders. Third-party auditors are prohibited from interfering with CDC's ability to inspect and conduct oversight under this framework, including but not limited to interfering with CDC's ability to interview cruise ship crew and personnel or visually inspect and oversee collection of laboratory specimens and laboratory testing.

Requirements for Protection of Crew for Cruise Ship Operators Operating or Intending to Operate Cruise Ships in U.S. Waters.

(a) A cruise ship operator subject to this Order must meet the requirements of this framework as a condition of obtaining or retaining controlled free pratique for operating a cruise ship in U.S. waters or if the cruise ship operator is operating a cruise ship outside of U.S. waters and intends for the ship to return to operating in U.S. waters while this Order remains in effect. These requirements must additionally be met as a condition of obtaining or retaining controlled free pratique for conducting a simulated voyage or applying for a COVID-19 Conditional Sailing Certificate.

(1) The cruise ship operator must have received a determination by CDC that a plan submitted in response to the No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations published at 85 FR 21004 (April 15, 2020) (i.e., “No Sail Order response plan”), as modified and extended July 16, 2020 (published at 85 FR 44085 (July 21, 2020)), and September 30, 2020 (published at 85 FR 62732 (October 5, 2020)) is complete and accurate, including having submitted to CDC a signed Acknowledgment of No Sail Order Response Plan Completeness and Accuracy.

(2) Cruise ships operating in U.S. waters must continue to submit the EDC form as specified in CDC technical instructions or orders. Cruise ship operators with ships that have not been in U.S. waters during the period of March 14 through October 31, 2020, or who voluntarily withdrew their ships during this time period, and who wish to operate those ships in U.S. waters during the period that this framework remains in effect, must additionally submit the EDC form during (at a minimum) the 28 days preceding those ships’ expected arrival in U.S. waters and continue to submit the EDC form after the ships’ entering U.S. waters.

(3) The cruise ship operator has observed and will continue to observe all elements of its No Sail Order response plan including by following the most current CDC recommendations and guidance for any public health actions related to COVID-19, or if any deviations from the plan

have occurred such deviations have been reported and corrective actions taken to the satisfaction of CDC.

(4) The cruise ship operator has arranged for and submitted and will continue to arrange for and submit such laboratory test results as may be required by CDC for every crew member on board ships operating in U.S. waters and/or operating outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in U.S. waters at any time while this Order remains in effect. Laboratory testing for every crew member must be conducted on a weekly basis or at such other intervals as required by CDC in technical instructions or orders. CDC may conduct oversight of specimen collection, testing, and laboratory procedures, as necessary.

(5) If the cruise ship received any ship-to-ship transfers in the last 28 days, crew were only transferred from a cruise ship with no confirmed COVID-19 or COVID-like illness during the 28 days before the transfer occurred.

(6) If the cruise ship received any land-based embarking crew, such crew were laboratory tested for COVID-19 upon embarkation and quarantined per CDC technical instructions or orders immediately upon embarking the ship.

(7) Following submission of an application for a COVID-19 Conditional Sailing Certificate, the cruise ship operator shall continue to follow these requirements for protection of crew pending approval of the operator's application.

(b) CDC may issue additional requirements through technical instructions or orders relating to a cruise ship operator's processes and procedures for protection of crew.

General Prohibition on a Cruise Ship Operator Commencing or Continuing Passenger Operations without a COVID-19 Conditional Sailing Certificate.

(a) A cruise ship operator shall not commence or continue any passenger operations in U.S. waters without a COVID-19 Conditional Sailing Certificate issued by CDC that meets the requirements in this framework for each cruise ship that the cruise ship operator intends to operate with passengers in U.S. waters.

(b) A cruise ship operator shall not violate the terms or conditions of a COVID-19 Conditional Sailing Certificate issued pursuant to this framework.

(c) As a condition of obtaining or retaining a COVID-19 Conditional Sailing Certificate, the cruise ship operator must be in compliance with CDC's standards for mitigating the risk of COVID-19 onboard the cruise ship as set forth in this framework and in CDC technical instructions or orders.

Agreement with Port and Local Health Authorities.

(a) As a condition of obtaining or retaining controlled free pratique for conducting a simulated voyage or obtaining and retaining a COVID-19 Conditional Sailing Certificate, a cruise ship operator must document the approval of all U.S. port and local health authorities where the ship intends to dock or make port during a simulated voyage or a restricted passenger voyage. Such written approval must include the following:

(1) A medical care agreement between the cruise ship operator and health care entities, addressing evacuation to onshore hospitals for passengers and crew in need of care, in accordance with CDC technical instructions and orders.

(2) A housing agreement between the cruise ship operator and one or more shoreside facilities for isolation and quarantine of COVID-19 cases and close contacts, respectively, identified from the day of embarkation through disembarkation for each voyage, in accordance with CDC technical instructions and orders.

(3) A port agreement between the cruise ship operator and port authority to determine the number of cruise ships at any single port in order to not overburden the public health response resources of any single jurisdiction in the event of a COVID-19 outbreak.

Minimum Standards for Simulated Voyages Prior to Issuance of COVID-19 Conditional Sailing Certificate.

(a) As a condition of applying for a COVID-19 Conditional Sailing Certificate, a cruise ship operator must have successfully conducted a simulated voyage or series of simulated voyages demonstrating the cruise ship operator's ability to mitigate the risks of COVID-19 onboard its cruise ship. A simulated voyage must meet the following requirements:

(1) The cruise ship operators shall inform volunteer passengers in writing that they are participating in a simulation of unproven and untested health and safety protocols for purposes of simulating a cruise ship voyage and that sailing during a pandemic is an inherently risky activity.

(2) All volunteer passengers must be at least eighteen years old or older. The cruise ship operator must also obtain from all volunteer passengers a written certification from a healthcare provider that the volunteer passenger has no pre-existing medical conditions that would place that individual at high risk for COVID-19 as determined through CDC guidance. CDC may issue additional requirements through technical instructions or orders relating to a cruise ship operator's obligation to screen for volunteer passengers who may be at high risk for COVID-19.

(3) The cruise ship operator must conduct any simulation on a consensual basis and not as a condition of employment or in exchange for consideration or future reward. The cruise ship operator must document the informed consent of all participants in writing.

(4) The cruise ship operator must embark additional crew members beyond safe minimum manning levels only as determined through CDC technical instructions or orders.

(5) The cruise ship operator must design and conduct a simulated voyage insofar as practicable to test the efficacy of the cruise ship operator's ability to mitigate the risks of COVID-19 onboard its cruise ship.

(6) The cruise ship operator must conduct a monitored observation period and laboratory testing of volunteer passengers, as directed in CDC technical instructions or orders, prior to embarking volunteer passengers on a simulated voyage.

(7) A simulated voyage must include the following simulated activities:

- (i) embarkation and disembarkation procedures, including terminal check-in,
- (ii) on board activities, including at dining and entertainment venues,
- (iii) private island shore excursions, if any are planned during restricted passenger voyages,
- (iv) evacuation procedures,
- (v) transfer of symptomatic passengers or crew, or those who test positive for SARS-CoV-2, from cabins to isolation rooms,
- (vi) quarantine of all remaining passengers and non-essential crew, and
- (vii) other activities as may be listed in CDC technical instructions and orders.

(8) The cruise ship operator must meet standards for hand hygiene, face coverings, and social distancing for passengers and crew, as well as ship sanitation, as may be required by CDC technical instructions or orders.

(9) The cruise ship operator must modify meal service and entertainment venues to facilitate social distancing during the simulated voyage.

(10) The cruise ship operator must conduct laboratory testing of all passengers and crew on the day of embarkation and the day of disembarkation as required by CDC technical instructions or orders. Laboratory test results must be available prior to passengers embarking

and prior to passengers and crew departing for their final destinations after disembarking the ship. Crew and passengers must also be laboratory tested again post-disembarkation as required by CDC technical instructions or orders. Based on public health considerations, CDC may also require additional laboratory testing of passengers and crew and reporting of results, including during a voyage, as required by CDC technical instructions or orders.

(11) The cruise ship operator must immediately conduct laboratory testing of any passengers and crew who report illness consistent with COVID-19 during the simulated voyage with rapid point-of-care results as required by CDC technical instructions or orders. Identified close contacts of cases must also be laboratory tested with rapid point of care results.

(12) CDC may require the cruise ship operator to immediately end the simulated voyage and take other action to protect the health and safety of volunteer passengers and crew if COVID-19 is detected during the simulation.

(13) The cruise ship operator must document any deficiencies in its health and safety protocols through an “after-action” report and address how the cruise ship operator intends to address those deficiencies prior to applying for a COVID-19 Conditional Sailing Certificate. This after-action report must also include test results for any volunteer passengers or crew on the simulated voyage. The after-action report must be submitted to the CDC as soon as practicable at the end of the simulation and as part of the cruise ship operator’s application for a COVID-19 Conditional Sailing Certificate.

(14) Based on CDC’s review of the after-action report and/or cruise ship operator’s application for a COVID-19 Conditional Sailing Certificate, CDC may request that the cruise ship operator modify its practices or procedures and/or engage in additional simulated voyages prior to the issuance of the COVID-19 Conditional Sailing Certificate.

(b) Prior to conducting a simulated voyage in accordance with this section, the cruise ship operator shall provide written notice and request CDC's approval to conduct the simulation. Such written notice must be provided prior to the simulation and specify the time, location, contact information for all individuals or parties involved, and protocols or practices to be simulated.¹⁷

(c) A cruise ship operator shall not apply for approval to conduct a simulated voyage until all of CDC's requirements relating to the protection of crew onboard ships in U.S. waters have been satisfied. The cruise ship operator's responsible officials must sign the application for permission to conduct a simulation and certify under 18 U.S.C. § 1001 that all of CDC's requirements relating to the protection of crew onboard cruise ships in U.S. waters have been satisfied.

(d) CDC will respond to the written notice and request for approval to conduct a simulation in writing in a timely manner. CDC may deny the request to conduct a simulation if the cruise ship operator is not in compliance with any provision of this framework, technical instructions, or orders, or if in CDC's determination the simulation does not provide adequate safeguards to minimize the risk of COVID-19 for all participants.

(e) CDC may conduct such oversight and inspection of simulated voyages as it deems necessary in its discretion, including through in-person or remote means allowing for visual observation.

(f) CDC may issue additional requirements through technical instructions or orders relating to a cruise ship operator's processes and procedures for conducting and evaluating a simulated voyage prior to applying for a COVID-19 Conditional Sailing Certificate.

¹⁷ This written notice should be submitted at least 30 calendar days prior to the date on which the cruise ship operator proposes to conduct the simulation.

Applying for a COVID-19 Conditional Sailing Certificate.

(a) A cruise ship operator must submit the following to CDC prior to commencing restricted passenger operations:¹⁸

(1) A completed CDC registration/application form that must include the signatures of the cruise ship operator's responsible officials;

(2) The name, titles, and contact information for the cruise ship operator's responsible officials and of any third-party auditors.

(3) A completed statement of intent stating the name, carrying capacity for passengers and crew, itinerary, ports of call, length of voyage, and expected onboard or shoreside activities, for the cruise ship that the cruise ship operator intends to have certified for restricted passenger operations.

(4) A copy of the USCG Certificate of Inspection issued in accordance with 46 CFR § 2.01-5 that was in effect for the six months preceding the application.

(5) A certification statement signed under 18 U.S.C. § 1001 by the responsible officials attesting that the cruise ship operator has complied and remains in compliance with CDC's crew protection requirements of prior to applying for a COVID-19 Conditional Sailing Certificate.

(6) A certification statement signed under 18 U.S.C. § 1001 by the responsible officials attesting that the cruise ship operator has adopted health and safety protocols that meet CDC's standards for mitigating the risk of COVID-19 among passengers and crew onboard the cruise ship that will be commencing restricted passenger operations, and will modify these protocols as needed to protect the public's health as required by CDC technical instructions or orders.

¹⁸ These materials should be submitted at least 60 calendar days prior to the date on which the cruise ship operator proposes to commence restricted passenger operations.

(7) A certification statement signed under 18 U.S.C. § 1001 by the responsible officials attesting that the cruise ship operator has sufficient medical and point of care laboratory capabilities and staff on board the cruise ship that will be commencing restricted passenger operations to manage severe COVID-19 cases and outbreaks in exigent circumstances as required by CDC technical instructions or orders.

(8) A certification statement signed under 18 U.S.C. § 1001 by the responsible officials attesting that the cruise ship operator is in compliance with the other requirements contained in this framework for mitigating the risk of COVID-19 on board cruise ships and agrees to continue to comply with these requirements.

Review of an Application for a COVID-19 Conditional Sailing Certificate.

(a) Upon receiving the documentation required by this framework, CDC will review the application for completeness. Based on CDC's determination as to whether the cruise ship operator has met CDC's standards for mitigating the risk of COVID-19 onboard the cruise ship for which the operator intends to commence restricted passenger operations, it shall grant or deny the application. If CDC requires additional information to ascertain whether the cruise ship operator has met CDC's standards for mitigating the risk of COVID-19 on board cruise ships, or if it determines the application to be incomplete, it may hold the application in abeyance pending the submission of such additional information as required by CDC to make such a determination. Applications that are denied may be administratively appealed as described in this framework.

(b) CDC may limit the terms or conditions of a cruise ship operator's COVID-19 Conditional Sailing Certificate in regard to passenger or crew capacity, itinerary, ports of call, length of voyage, onboard or shoreside activities, or in regard to any other passenger, crew, or

cruise ship operations, as needed to the health and safety of passengers and crew or the public's health.

(c) As a condition of obtaining or retaining a COVID-19 Conditional Sailing Certificate, the cruise ship operator must upon request make its properties and records available for inspection to allow CDC to ascertain compliance with this framework. Such properties and records include but are not limited to vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, and employee and passenger health records. The cruise ship operator must also make any crew member or other personnel involved in the operation of a cruise ship available for interview by CDC.

(d) As a condition of obtaining or retaining a COVID-19 Conditional Sailing Certificate, CDC may require a cruise ship operator to submit proof of having been inspected by any other agency or entity with authority, jurisdiction, or oversight over any aspect of a cruise ship operator's operations.

(e) As a condition of obtaining or retaining a COVID-19 Conditional Sailing Certificate, cruise ship operators must establish mechanisms to ensure compliance, including reporting mechanisms to notify CDC and USCG in writing within 24 hours of the occurrence of any deviations, whether intentional, or as a result of error or omission, and take corrective steps to rectify those deviations.

(f) As a condition of obtaining or retaining a COVID-19 Conditional Sailing Certificate, cruise ship operators must comply with the requirements of this framework. These requirements apply to any cruise ship operating in U.S. waters and to cruise ships operating outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in U.S. waters at any time while Order remains in effect.

Amendment or Modification of COVID-19 Conditional Sailing Certificate.

(a) A cruise ship operator may seek to amend or modify a COVID-19 Conditional Sailing Certificate issued under this framework by submitting such amendment or modification to CDC for review and a determination in accordance with this section.

(b) CDC will review the cruise ship operator's request to amend or modify a COVID-19 Conditional Sailing Certificate and either grant or deny the request in writing. If CDC requires additional information to ascertain whether the cruise ship operator's proposed amendment or modification meets CDC's standards for mitigating the risk of COVID-19 on board cruise ships, or if it determines the request to be incomplete, it may hold the request in abeyance pending the submission of such additional information as required by CDC to make such a determination.

(c) CDC may require any cruise ship operator to amend or modify a COVID-19 Conditional Sailing Certificate based on public health considerations specific to the cruise ship, cruise ship operator, or affecting the health or safety of cruise travel as a whole.

(d) Denials of requests to amend or modify a COVID-19 Conditional Sailing Certificate are subject to administrative review as described in this framework.

Minimum Standards for Restricted Passenger Voyages as a Condition of Obtaining and Retaining a COVID-19 Conditional Sailing Certificate.

(a) As a condition of obtaining and retaining a COVID-19 Conditional Sailing Certificate, a cruise ship operator must meet the following minimum standards:

(1) The cruise ship operator must in marketing materials, on its website, and in offerings for voyages, notify prospective passengers prior to accepting a reservation of any CDC travel advisory, warning, or recommendation relating to cruise travel. Such notification must further advise prospective passengers that, if a threshold of COVID-19 is detected on board the cruise

ship during a voyage, the voyage will be ended immediately and the ship returned to the U.S. port of embarkation, and their subsequent travel, including their return home, may be restricted or delayed.

(2) The cruise ship operator must not sail or offer to sail on an itinerary longer than 7 days. CDC may shorten or lengthen the number of days permitted to sail based on public health considerations and as set forth in technical instructions or orders.

(3) The cruise ship operator must screen passengers and crew before they embark for signs and symptoms or known exposure to COVID-19 and deny boarding to anyone who is suspected of having COVID-19 or is an identified contact of a confirmed or suspected case, in accordance with CDC technical instructions or orders.

(4) The cruise ship operator must conduct laboratory testing of all passengers and crew on the day of embarkation and the day of disembarkation in accordance with CDC technical instructions or orders. Laboratory test results must be available prior to passengers embarking and prior to passengers and crew departing for their final destinations after disembarking the ship.

(5) The cruise ship operator must immediately conduct laboratory testing of any passengers and crew who report illness consistent with COVID-19 during the voyage with rapid point of care results as required by CDC technical instructions or orders. Identified close contacts of cases must also be laboratory tested with rapid point of care results.

(6) The cruise ship operator shall report syndromic surveillance and all laboratory test results using CDC's EDC form as required by CDC technical instructions or orders.

(7) The cruise ship operator must meet standards for hand hygiene, face coverings, and social distancing for passengers and crew, as well as ship sanitation, as required by CDC technical instructions or orders.

(8) The cruise ship operator must modify meal service and entertainment venues to facilitate social distancing.

(b) In light of public health considerations and based on evidence gained through review and evaluation of cruise operators' practices and procedures, including through simulated voyages, CDC may require the following:

(1) A monitored observation period of passengers prior to embarking.

(2) Post day of disembarkation laboratory testing of passengers and crew.

(3) Additional laboratory testing of passengers and crew and reporting of results during a voyage.

(c) CDC may issue additional technical instructions or orders regarding health and safety standards for restricted passenger voyages.

Minimum Standards for Management of Passengers and Crew from COVID-19-affected Cruise Ships for Restricted Passenger Voyages.

(a) Based on a threshold of COVID-19 being detected in passengers or crew, as determined through CDC technical instructions or orders, a cruise ship operator must immediately take the following actions:

(1) Conduct such notifications of passengers, crew members, and other government entities as CDC may require.

(2) Immediately end the restricted passenger voyage, cancel future restricted passenger voyages until directed by CDC that such voyages may resume, and return the ship to the U.S. port of embarkation.

(3) Immediately isolate any sick or infected passengers and crew in single occupancy cabins with private bathrooms and quarantine all remaining passengers and non-essential crew.

(4) Disembark and evacuate passengers and crew only in such a manner as prescribed in the cruise ship operator's preexisting port and local health authority agreements.

(5) Arrange to disembark and transport passengers and crew using noncommercial transportation or other transportation in accordance with CDC's technical instructions and orders.

(6) Instruct disembarking passengers and crew to stay home and continue to practice social distancing after reaching their final destination as per CDC technical instructions or orders.

(7) Inform ship pilots, ground transportation, air charter operators, and other agencies with relevant jurisdiction that COVID-19 has been detected in passengers or crew and confirm that the operators have plans in place to notify and protect the health and safety of their staff (e.g., drivers, air crews).

(b) CDC may issue additional technical instructions or orders regarding what measures cruise ship operators must take in the event that COVID-19 is detected in passengers or crew.

Denials, Suspension, Revocation, and Reinstatement of a Cruise Ship Operator's COVID-19 Conditional Sailing Certificate.

(a) CDC may deny an application for a COVID-19 Conditional Sailing Certificate, or revoke, or suspend a COVID-19 Conditional Sailing Certificate if:

(1) the cruise ship operator is not in compliance with CDC's standards for mitigating the risk of COVID-19 on board cruise ships; or

(2) the cruise ship operator is not in compliance with the terms of its COVID-19 Conditional Sailing Certificate; or

(3) necessary to protect human health or safety based on public health considerations specific to the particular cruise ship operator, cruise ship, or affecting cruise travel as a whole.

(b) CDC may reinstate a suspended or revoked COVID-19 Conditional Sailing Certificate after:

(1) inspecting the cruise ship operator's properties and records, including, but are not limited to, its vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, and employee and passenger health records;

(2) conferring with the cruise ship operator, responsible officials, third-party auditors, or other persons under the cruise ship operator's employ; and

(3) receiving information and written assurances from the cruise ship operator and/or its responsible officials that any deficiencies have been rectified and actions taken to ensure future compliance.

Administrative review.

(a) A cruise ship operator may appeal a denial of its application for a COVID-19 Conditional Sailing Certificate or a revocation or suspension of its COVID-19 Conditional Sailing Certificate based on specific factors particular to that operator.

(b) The cruise ship operator's appeal must be in writing, state the factual basis for the appeal, and be submitted to the CDC Director within 30 calendar days of the decision.

(c) The CDC Director's decision will be issued in writing and will constitute final agency action. Prior to deciding upon an appeal, the Director may further investigate the reasons for the denial, revocation, or suspension, including by conferring with the cruise ship operator, responsible officials, third-party auditors, or other persons under the cruise ship operator's employ.

Initial Phase COVID-19 Testing Requirements for Protection of Crew

CDC will take a phased approach to resuming passenger operations onboard cruise ships and considers adequate crew safeguards an integral part of its initial phases. Accordingly, it is further

ORDERED:

Shoreside COVID-19 Laboratory Screening Testing of All Crew.

- 1) Within 60 days of the effective date of this Order,¹⁹ cruise ship operators must collect clinical specimens from all crew currently onboard their cruise ships and have those specimens immediately transported and tested by a shoreside laboratory facility. This testing must be conducted by a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory using reverse transcriptase polymerase chain reaction (RT-PCR) tests that are approved, cleared, or authorized for emergency use by the U.S. Food and Drug Administration (FDA).

- 2) To help ensure the validity of sampling, testing, and test results, cruise ship operators must contact CDC at eoevent349@cdc.gov at least 7 calendar days prior to collecting specimens and conducting testing. CDC must approve the cruise ship operator's selection of a CLIA-certified laboratory and the cruise ship operator's procurement of specimen

¹⁹ For cruise ship operators with ships that have not been in U.S. waters during the period of the No Sail Order or voluntarily withdrew their ships, the 60-day period will begin upon: (1) CDC confirming to the cruise ship operator in writing that the operator has a complete and accurate NSO response plan, including having submitted to CDC a signed *Acknowledgment of No Sail Order Response Plan Completeness and Accuracy*; and (2) submission of the EDC form for the 28 days preceding the cruise ship's expected arrival in U.S. waters.

collection kits. Include “Laboratory Screening Testing of All Crew Onboard SHIP NAME” in the subject line as part of your request for CDC approval.

- 3) CDC’s response to the cruise ship operator’s email may include additional information regarding best practices that may assist cruise ship clinicians or public health staff in collecting and transporting crew specimens. CDC may also oversee the onboard collection of crew specimens through remote means allowing for visual observation.
- 4) Cruise ship operators must report all laboratory results in aggregate to CDC through the Enhanced Data Collection (EDC) form.

Onboard COVID-19 Diagnostic Testing Capabilities for Symptomatic Travelers (Crew and Future Passengers)

- 1) During this 60-day period, cruise ship operators in coordination with CDC must develop onboard testing capabilities to test all symptomatic travelers (crew and future passengers) for COVID-19 and close contacts. After this 60-day period, laboratory testing for every crew member must be conducted on a weekly basis or at such other intervals as required by CDC in technical instructions or orders.
- 2) All cruise ships must procure rapid RT-PCR point-of-care equipment to test symptomatic travelers. This instrument must be CLIA-waived and have been evaluated on the FDA reference panel for SARS-CoV-2 and demonstrated a lower limit of detection correlating to higher sensitivity. Cruise ship operators must contact CDC prior to procuring this

equipment. Antigen testing is not recommended at this time because it is more likely to miss cases of SARS-CoV-2 infection (i.e., lower sensitivity) when compared to RT-PCR testing.

- 3) Cruise ship medical clinic staff must be competent in specimen collection, be able to properly use testing equipment, follow all manufacturer's instructions, and have access to and use recommended personal protective equipment (PPE) for specimen collection and handling. CDC may ensure competency by conducting oversight of these practices through remote means allowing for visual observation. In addition, cruise ship operators must maintain onboard SARS-CoV-2 testing equipment to manufacturer's specifications.
- 4) Once testing equipment has been obtained and cruise ship medical clinic staff are properly trained in its use, all symptomatic crew onboard the cruise ship must be tested for SARS-CoV-2 infection immediately upon notifying medical staff of symptom onset. These results must be reported to CDC in aggregate through the EDC form.

Shoreside COVID-19 Laboratory Screening Testing of All Embarking Crew

- 1) On the day of crew members' embarkation, cruise ship operators must collect specimens for SARS-CoV-2 testing from all embarking land-based crew. Cruise ship operators must immediately transport the specimens to a CLIA-certified laboratory for testing.
- 2) This laboratory must use an RT-PCR test that has been approved, cleared, or authorized for emergency use by FDA. Cruise ship operators must report results in aggregate to

CDC through the EDC form. CDC must approve the cruise ship operator's selection of a CLIA-certified laboratory.

- 3) All embarking land-based crew must be immediately quarantined onboard for 14 days. Those who test positive must be isolated until criteria are met for discontinuation of isolation according to the most current CDC guidance. CDC may also oversee the collection of specimens, or the quarantine or isolation of embarking crew, through remote means allowing for visual observation.

Continued Compliance with No Sail Order (NSO) Response Plans

- 1) Cruise ship operators must continue to follow their cruise lines' complete, accurate, and acknowledged NSO response plans per the No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations published at 85 FR 21004 (April 15, 2020) (i.e., "No Sail Order response plan"), as modified and extended July 16, 2020 (published at 85 FR 44085 (July 21, 2020)), and September 30, 2020 (published at 85 FR 62732 (October 5, 2020)).
- 2) Cruise ship operators must also continue to follow CDC's Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew and COVID-19 Color-coding System for Cruise Ships, which may be modified or updated as needed. CDC will notify cruise ship operators of any updates. Ship-to-ship crew transfers and embarkations may continue to impact ships' color-coding status. For additional information about other

public health preventive measures, such as social distancing, mask use, and cabin occupancy, refer to CDC's Interim Guidance.

Effective Date and Signature

This Order is effective upon signature and shall remain in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID-19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the order based on specific public health or other considerations; or (3) November 1, 2021.

In testimony whereof, the Director, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, has hereunto set his hand at Washington, D.C., this 30th day of October 2020.

A handwritten signature in black ink that reads "Robert R. Redfield". The signature is written in a cursive, flowing style.

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention

EXHIBIT 2

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)**

**ORDER UNDER SECTIONS 361 & 365
OF THE PUBLIC HEALTH SERVICE ACT (42 U.S.C. §§ 264, 268)
AND
42 CODE OF FEDERAL REGULATIONS
PART 70 (INTERSTATE) AND PART 71 (FOREIGN):
NO SAIL ORDER AND OTHER MEASURES RELATED TO OPERATIONS**

Applicability

This Notice of No Sail Order and Other Measures Related to Operations shall apply only to the subset of carriers¹ described below and hereinafter referred to as “cruise ships,” except this Order shall not apply to any cruise ship that voluntarily suspends operations for the period of this Order:

All commercial, non-cargo,² passenger-carrying vessels operating in international, interstate, or intrastate waterways and subject to the jurisdiction of the United States with the capacity to carry 250³ or more individuals (passengers and crew) with an itinerary anticipating an overnight stay onboard or a twenty-four (24) hour stay onboard for either passengers or crew.⁴

General Background

COVID-19 is a communicable disease caused by a novel (new) coronavirus, SARS-CoV-2, that was first identified as the cause of an outbreak of respiratory illness that began in Wuhan, China.

¹ Carrier is defined by 42 C.F.R. § 71.1 to mean “a ship, aircraft, train, road vehicle, or other means of transport, including military.”

² Given the substantial risk of person-to-person transmission of COVID-19, as opposed to transmission via indirect contact, this Order is currently limited to passenger, non-cargo vessels.

³ Based on substantial epidemiological evidence related to congregate settings and mass gatherings, this Order suspends operation of vessels with the capacity to carry 250 individuals or more. Evidence shows that settings as small as nursing homes or movie theaters can proliferate the spread of a communicable disease. As the numbers of passengers and crew onboard a ship increases, certain recommended mitigation efforts such as social distancing become more difficult to implement. In light of the demonstrated rapid spread of this communicable disease in current cruise ship settings, application of this Order to vessels carrying 250 or more individuals is a prudent and warranted public health measure. Moreover, the management of current coronavirus cases in addition to existing seasonal care needs (e.g., influenza) has placed an extreme burden on the public health and healthcare systems and this Order will help avoid further stressing those systems.

⁴ This order shall not apply to vessels operated by a U.S. Federal or State government agency. Nor shall it apply to vessels being operated solely for purposes of the provision of essential services, such as the provision of medical care, emergency response, activities related to public health and welfare, or government services, such as food, water, and electricity.

The virus is thought to spread primarily by person-to-person contact through respiratory droplets produced when an infected person coughs or sneezes; it may also spread through contact with contaminated surfaces or objects. Manifestations of severe disease have included severe pneumonia, acute respiratory distress syndrome (ARDS), septic shock, and multi-organ failure. According to the World Health Organization (WHO), approximately 3.6% of reported COVID-19 cases have resulted in death globally. This mortality rate is higher among the elderly or those with compromised immune systems. Older adults and people who have severe chronic medical conditions like heart, lung, or kidney disease are also at higher risk for more serious COVID-19 illness. Early data suggest older people are twice as likely to have serious COVID-19 illness.

On January 30, 2020, the Director General of the WHO declared that the outbreak of COVID-19 constitutes a Public Health Emergency of International Concern under the International Health Regulations. The following day, the Secretary of the Department of Health and Human Services (HHS) declared that COVID-19 constitutes a public health emergency under the Public Health Service Act. To date, CDC has issued Level 3 Travel Health Notices recommending that travelers avoid all nonessential travel to China, Iran, South Korea, and most of Europe; the U.S. Department of State has issued a global Level 3 Health Advisory directing U.S. citizens to reconsider all travel abroad due to the global impact of COVID-19 and Level 4 Travel Advisories (Do Not Travel) for China, Iran, and certain parts of Italy. In addition, CDC has recommended that travelers, particularly those with underlying health conditions, avoid all cruise ship travel worldwide; the U.S. Department of State has similarly issued guidance that U.S. citizens should not travel by cruise ship at this time. As of March 11, 2020, the President of the United States has suspended entry to the U.S. by most foreign nationals who have recently visited China, Iran, and most of Europe due to COVID-19. On March 11, 2020, the WHO declared the COVID-19 outbreak a pandemic. As of March 13, 2020, there have been over 132,000 cases of COVID-19 globally in over 122 locations resulting in over 4,950 deaths; more than 1,620 cases have been identified in the United States, with new cases being reported daily and over 41 deaths due to the disease. A Presidential Declaration of National Emergency concerning COVID-19 was issued on March 13, 2020.

Global efforts to slow transmission have included drastic control measures with substantial societal and economic impact. Countries such as Russia, Australia, the Philippines, Japan, Israel, and the United States have imposed stringent restrictions on travelers who have recently been in China. Similar travel restrictions have since been imposed on individuals from countries experiencing substantial outbreaks, including Iran, South Korea, and Europe. In many countries, including the United States, citizens, permanent residents, and their close relatives returning from areas known to have high rates of infection are being requested to self-quarantine for 14 days (a period estimated to encompass the incubation period for the virus) following return from countries with sustained community transmission. Despite these unprecedented global efforts at containment, cases of COVID-19 have been shown to rapidly propagate, crossing international borders with ease. For example, the Islamic Republic of Iran has seeded at least 97 COVID-19 cases in 11 other countries, as reported by the WHO, and as of March 9, 2020, the Schengen Area of Europe has exported 201 COVID-19 cases to 53 countries.

In the United States, community transmission has occurred in Washington State, California, and New York. CDC is closely monitoring COVID-19 transmission and is supporting state and local

health departments in conducting contact tracing investigations of confirmed COVID-19 cases identified in the United States. These investigations are complex and resource intensive; persons identified as infected or at-risk can require observation, movement restriction (such as isolation or quarantine), clinical evaluation, and care. Public health authorities in the United States are working concurrently to contain the spread of the disease and mitigate its impact.

Risk of Transmission on Cruise Ships

Cruise ships often involve the movement of a number of people in closed and semi-closed settings. Cruises vary in size, with larger cruises involving populations of more than 4,000 passengers and crew. Like other close-contact environments, cruise ships facilitate transmission of COVID-19.

There are several features of cruise ships that increase the risk of COVID-19 transmission. A hallmark of cruise travel is the number and variety of person-to-person contacts an individual passenger may have daily. The dynamics of passenger-to-passenger, passenger-to-crew, crew-to-passenger, and crew-to-crew intermingling in a semi-closed setting are particularly conducive to SARS-CoV-2 spread, resulting in high transmission rates. Cruises include frequent events that bring passengers and crew close together, including group and buffet dining, entertainment events, and excursions. Cruise ship cabins are small, increasing the risk of transmission between cabinmates. Close quartering is a particular concern for crew, who typically eat and sleep in small, crowded spaces. Infection among crew members may lead to transmission on sequential cruises on the same vessel because crew members may continue working and living onboard the ship from one cruise to the next. Crew from one ship may in turn serve onboard multiple different ships for subsequent voyages, which also has the potential to amplify transmission.

Transmission of COVID-19 on cruise ships may also be amplified by difficulty decontaminating numerous surfaces in common areas. Contamination of frequently touched surfaces, such as door handles and faucets in public toilet rooms, elevator buttons, handrails in stairs and passageways, and utensils/dispensing mechanisms (for beverages) in self-service buffets, etc., is also likely to be a significant factor in transmission. Less obvious examples of frequently touched surfaces, include playing cards, slot machine levers, and chips in the casino; computer keyboards in the internet café; books, puzzles, and games in the library; gym equipment; counters and surfaces in gift shops; and the cruise card used by passengers to pay/register for everything on board and exit/enter the ship in port. The high volume of people on board a cruise ship and wealth of high-touch surfaces make successful control of this method of transmission very difficult.

Moreover, the nature of cruise travel presents additional opportunities for spread of the disease to ports of calls and passengers' home communities. During a cruise, disembarkation of passengers at sequential ports of call under uncontrolled conditions may lead to disease transmission in those ports. Once a cruise concludes, passengers residing in different countries or throughout the United States may require air transportation or other types of common carriers to return home. Return of disembarked infected passengers to their communities could lead to widespread, interstate disease transmission.

Quarantine and isolation measures are difficult to implement effectively onboard a cruise ship and only occur after an infection has already been identified onboard a cruise. If ships are at capacity, it may not be feasible to fully separate ill and well persons onboard the ship, particularly among the crew. Because crew are required to continue working to keep a ship safely operating, effective quarantine for crew is particularly challenging.

Already Observed Impact of Cruise Ship Travel in General and in the U.S.

Cruise ship travel has already been associated with a number of COVID-19 clusters and outbreaks, including on the Diamond Princess (Asia) and the Grand Princess (California to Mexico, California to Hawaii). The threat of spread is not limited to larger cruise ships. An outbreak onboard a Nile River cruise with 171 passengers and crew (29 of which were American citizens) resulted in 45 confirmed COVID-19 cases (3 of which are American citizens). Many of these passengers returned home before any notifications about COVID-19 were provided, potentially spreading the disease to their home communities. Evidence of COVID-19 transmission onboard six similar Nile River cruise ships, each carrying approximately 100 passengers, illustrates that even ships with moderate numbers of passengers and crew onboard carry a substantial risk of disease transmission and outbreak.

The initial stages of the COVID-19 epidemic were marked by the outsized role of a single cruise ship, the Diamond Princess in Yokohama, Japan, which for a period of 18 days was the setting for the largest number of cases outside the original epicenter in China. The outbreak of COVID-19 onboard the Diamond Princess demonstrates the speed and extent of disease transmission that can occur onboard cruise ships. Despite quarantine and isolation efforts, more than 700 cases of infection with the virus that causes COVID-19 were identified among Diamond Princess passengers and crew during the three weeks following the identification of one case of COVID-19 in a person who was symptomatic before leaving the ship. There are several cases of severe disease associated with the Diamond Princess, including at least six deaths. Additionally, approximately half of the infected passengers did not report symptoms at the time their infections were diagnosed.

On March 4, 2020, Placer County, California officials reported the death of a passenger who had been onboard the Grand Princess cruise ship during a voyage from February 11-21, 2020 (Sailing A) and was a confirmed COVID-19 case. As of March 7, 2020, there were 22 presumptive positive cases of COVID-19 among persons who were onboard Sailing A. The Grand Princess left San Francisco for a second sailing on February 21 (Sailing B). Sixty-eight passengers and most of the crew from Sailing A were also on Sailing B. While testing of those who were onboard Sailing B continues, to date, 22 crew and 8 passengers have tested positive for COVID-19. As a result of the outbreak onboard the Grand Princess, the Federal government engaged in a massive effort to disembark and quarantine American passengers from the ship on four military bases to help prevent further transmission to the passengers' home communities. Passengers from Sailing A were from more than 30 U.S. states and 25 countries; Sailing B included passengers from over 50 countries. More than 70 persons from this voyage have reported symptoms and require assessment and evaluation and additional confirmed cases in multiple states/countries are anticipated.

The Director Has Reason to Believe That Cruise Ship Travel May Continue to Introduce, Transmit, or Spread COVID-19

Cruise ship travel markedly increases the risk and impact of the COVID-19 disease outbreak within the United States. Disembarkation of passengers at sequential ports may lead to disease transmission in those ports. Return of disembarked infected passengers to their communities could lead to widespread disease transmission. Cases that have been confirmed to date may have led to secondary transmission, including in a healthcare worker. Furthermore, the passenger population of cruises often includes a substantial number of older adults, meaning there is higher risk for COVID-19 morbidity and mortality. Industry trade publications report that 51% of cruise ship passengers are over the age of 50. The median age of passengers onboard the Grand Princess Sailing B, for example, was 66 and 1,200 passengers on the ship were over age 70. Given these demographics, many cruise passengers are at high risk for severe disease if they become infected.

Beyond the risk to these individuals, the intensive care requirements for cruise ship passengers with severe disease stresses a healthcare system already overburdened and facing a shortage of beds needed for influenza and other seasonal and critical healthcare conditions. The addition of further cruise ship cases place healthcare workers at substantial increased risk. Specifically, these cases divert medical resources away from persons with other medical problems and other COVID-19 cases, consuming precious diagnostics, therapeutics, and protective equipment. Ongoing concerns with cruise ship transmission also draw valuable resources away from the immense Federal, state, and local effort to contain and mitigate the spread of COVID-19. Safely evacuating, triaging, quarantining, and repatriating cruise ship passengers involves complex logistics, incurs financial costs at all levels of government, and diverts resources away from larger efforts to suppress or mitigate the virus.

Coordination Efforts with the Cruise Ship Industry

To address the continued and significant risks and burdens posed by ongoing cruise ship operations, CDC and other Federal agencies have engaged with representatives from Cruise Lines International Association (“CLIA”), the leading industry trade group. To that end, CLIA members and certain individual cruise lines have voluntarily taken steps to try to mitigate the impact of the spread of COVID-19. On March 13, 2020, CLIA and their associated members announced that all member cruise lines would voluntarily suspend cruise ship operations from U.S. ports of call for 30 days as public health officials and the Federal government continue to address COVID-19. The Federal government recognizes the enormity and importance of this action taken by CLIA and the commitment it demonstrates to protecting the health of both cruise ship passengers and the public at large. Following the example set by CLIA members, additional cruise lines have also voluntarily suspended operations from U.S. ports of call. Although the CLIA members and the additional cruise lines implementing a voluntary suspension of operations represent a large majority of the cruise industry, not all cruise lines or ships have announced a voluntary suspension of operations or that they will follow the important example set by CLIA members. This Order is intended to cover and specifically apply to those cruise lines or ships that do not undertake a voluntary suspension of operations. As a result, this Order

specifically excludes from applicability any cruise line or ship that voluntarily suspends operations for the period of this Order, as CLIA members have done.

Findings and Immediate Action

Accordingly, and consistent with 42 C.F.R. § 71.32(b), the Director of CDC (“Director”) finds evidence to support a reasonable belief that cruise ships are or may become infected or contaminated with a quarantinable communicable disease.⁵ This reasonable belief is based on information from epidemiologic and other data regarding the nature and transmission of COVID-19 on cruise ships from the recent outbreaks onboard the Diamond Princess, Grand Princess, and other cruise ships. As a result, cruise ship passengers may be infected with or exposed to COVID-19 by virtue of having been onboard a cruise ship at a time when cases of COVID-19 are being reported in significant numbers globally and specifically on cruise ships, when testing is available.

The Director also finds that cruise ship travel may exacerbate the global spread of COVID-19. The scope of this pandemic is inherently and necessarily a problem that is international and interstate in nature, and cannot be controlled sufficiently by the cruise ship industry or individual state or local health authorities. Accordingly, under 42 C.F.R. § 70.2, the Director determines that measures taken or likely to be taken by state and local health authorities regarding COVID-19 onboard cruise ships are inadequate to prevent the further interstate spread of the disease.

The Director further determines that this Order provides public health authorities, in concert with the cruise ship industry, the necessary pause in operations to develop and implement an appropriate and robust plan to prevent and mitigate the spread of COVID-19, and acts to prevent the spread of the disease and ensure cruise ship passenger and crew health.

Therefore, in accordance with Sections 361 and 365 of the Public Health Service Act (42 U.S.C. §§ 264, 268) and 42 C.F.R. §§ 70.2, 71.32(b), for all cruise ships not voluntarily suspending operations for the period described below, it is ORDERED:

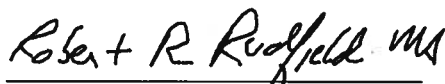
1. Cruise ship operators shall be allowed to disembark passengers and crew members at ports or stations only as directed by the United States Coast Guard (USCG), in consultation with HHS/CDC personnel and, as appropriate, as coordinated with Federal, state, and local authorities.
2. Cruise ship operators shall not reembark any crew member, except as approved by USCG, in consultation with HHS/CDC personnel, until further notice.
3. Cruise ship operators shall not embark any new passengers or crew, except as approved by USCG, or other Federal authorities as appropriate, in consultation with HHS/CDC personnel.

⁵ COVID-19 is a communicable disease for which quarantine is authorized under Section 361 of the Public Health Service Act (42 U.S.C. § 264) and 42 C.F.R. §§ 70.1, 71.1, as listed in Executive Order 13295, as amended by Executive Orders 13375 and 13674.

4. Cruise ship operators shall not commence or continue operations (e.g., shifting berths, moving to anchor, or discharging waste), except as approved by USCG, in consultation with HHS/CDC personnel, until further notice.
5. While in port, the cruise ship operator shall observe health precautions as directed by HHS/CDC personnel.
6. The cruise ship operator shall comply with all HHS/CDC, USCG, and other Federal agency instructions to follow CDC recommendations and guidance for any public health actions relating to passengers, crew, ship, or any article or thing on board the ship, as needed, including by making ship's manifests and logs available and collecting any specimens for COVID-19 testing.
7. This order does not prevent the periodic reboarding of the ship by HHS/CDC personnel and/or USCG and/or other Federal, state, or local agencies or the taking on of ships' stores and provisions under the supervision of HHS/CDC personnel and/or USCG.
8. This order does not prevent the ship from taking actions necessary to maintain the seaworthiness or safety of the ship, or the safety of harbor conditions, such as movement to establish safe anchorage, or as otherwise directed by USCG personnel.

This order is effective immediately and shall continue in operation for a period of thirty (30) days, unless rescinded earlier based on public health considerations. This order is subject to renewal and further modifications as needed.

In testimony whereof, the Director, Centers for Disease Control and Prevention, U.S. Department for Health and Human Services, has hereunto set his hand at Atlanta, Georgia, this 14th day of March, 2020.



Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention

EXHIBIT 3

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)**

**ORDER UNDER SECTIONS 361 & 365
OF THE PUBLIC HEALTH SERVICE ACT (42 U.S.C. 264, 268) AND
42 CODE OF FEDERAL REGULATIONS
PART 70 (INTERSTATE) AND PART 71 (FOREIGN):**

**MODIFICATION AND EXTENSION OF NO SAIL ORDER
AND OTHER MEASURES RELATED TO OPERATIONS**

Previous Order and Incorporation by Reference

This Order renews the No Sail Order and Other Measures Related to Operations signed by the CDC Director on March 14, 2020—subject to the modifications and additional stipulated conditions as set forth in this Order. This Order shall continue in operation until the earliest of (1) the expiration of the Secretary of Health and Human Services’ declaration that COVID-19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the order based on specific public health or other considerations; or (3) 100 days from the date of publication in the Federal Register. The findings and other evidence relied upon in issuing the March 14, 2020 Order are incorporated herein by reference. Any ambiguity between the March 14, 2020 Order, as modified by the current Order, shall be resolved in favor of the current Order.

Statement of Intent

This Order shall be interpreted and implemented in a manner as to achieve the following paramount objectives:

- Preservation of human life;
- Preventing the further introduction, transmission, and spread of COVID-19 into and throughout the United States;
- Preserving the public health and other critical resources of Federal, State, and local governments;
- Preserving hospital, healthcare, and emergency response resources within the United States; and
- Maintaining the safety of shipping and harbor conditions, including safety of personnel.

Applicability

This Modification and Extension of No Sail Order and Other Measures Related to Operations shall apply only to the subset of carriers¹ described below and hereinafter referred to as “cruise ships:”

¹ Carrier is defined by 42 CFR § 71.1 to mean, “a ship, aircraft, train, road vehicle, or other means of transport, including military.”

All commercial, non-cargo,² passenger-carrying vessels operating in international, interstate, or intrastate waterways and subject to the jurisdiction of the United States with the capacity to carry 250³ or more individuals (passengers and crew) with an itinerary anticipating an overnight stay onboard or a twenty-four (24) hour stay onboard for either passengers or crew.⁴

This Order shall additionally apply to any cruise ship that was previously excluded from the March 14, 2020 Order, by virtue of having voluntarily suspended operations.

“Operations” for purposes of this Order means any action by a cruise ship operator to bring or cause a cruise ship to be brought into or transit in or between any international, interstate, or intrastate waterways (e.g., shifting berths, moving to anchor, discharging waste, making port, or embarking or disembarking passengers or crew) subject to the jurisdiction of the United States.

“Operator” for purposes of this Order means the Master of the vessel (cruise ship) and any other crew member responsible for cruise ship operations and navigation, as well as any person or entity (including a corporate entity) that authorizes or directs the use of a cruise ship (e.g., as owner, lessee, or otherwise). A cruise ship operator may be either the cruise ship captain or the cruise line to which the cruise ship belongs, or both. The term “Operator” as used in this Order further incorporates the terms “company,” “designated person,” and “responsible person” as defined in 33 CFR. § 96.120.

Events Since the Issuance of March 14, 2020 Order

On March 14, 2020, the CDC Director issued a No Sail Order and Other Measures Related to Operations directing cruise ships not voluntarily suspending operations to comply with measures outlined by the CDC and U.S. Coast Guard. This followed a March 13, 2020, announcement by Cruise Lines International Association (CLIA), the leading industry trade group, that its members would voluntarily suspend cruise ship operations. On March 17, 2020, CDC issued a Level 3 Travel Warning that all travelers defer cruise travel worldwide based on widespread ongoing transmission of COVID-19.⁵ The suspension of a global tourism industry, such as the

² Given the substantial risk of person-to-person transmission of COVID-19, as opposed to transmission via indirect contact, this Order is currently limited to passenger, non-cargo vessels.

³ Based on substantial epidemiological evidence related to congregate settings and mass gatherings, this Order suspends operation of vessels with the capacity to carry 250 individuals or more. Evidence shows that settings as small as nursing homes or movie theaters can proliferate the spread of a communicable disease. As the numbers of passengers and crew onboard a ship increases, certain recommended mitigation efforts such as social distancing become more difficult to implement. In light of the demonstrated rapid spread of this communicable disease in current cruise ship settings, application of this Order to vessels carrying 250 or more individuals is a prudent and warranted public health measure. Moreover, the management of current coronavirus cases in addition to existing seasonal care needs (e.g., influenza) has placed an extreme burden on the public health and healthcare systems and this Order will help avoid further stressing those systems.

⁴ This order shall not apply to vessels operated by a U.S. Federal or State government agency. Nor shall it apply to vessels being operated solely for purposes of the provision of essential services, such as the provision of medical care, emergency response, activities related to public health and welfare, or government services, such as food, water, and electricity.

⁵ CDC, Traveler’s Health, *COVID-19 and Cruise Ship Travel*, at: <https://wwwnc.cdc.gov/travel/notices/warning/coronavirus-cruise-ship> (originally posted, March 17, 2020).

cruise line industry, does not happen instantaneously or easily. During the suspense of operations, the cruise line operators worked with both Federal, State, and local governments to disembark of over 250,000 passengers from more than 120 vessels. The cruise line operators continue discussions with Federal, State and local governments regarding the 114 vessels with over 93,000 crew either in or near U.S. ports. However, COVID-19 clusters and outbreaks continue to occur on and in connection with cruise ships.

There are a number of recent incidences of reported COVID-19 spread onboard cruise ships including the *Costa Magica*, *Costa Favolosa*, *Celebrity Eclipse*, *Disney Wonder*, *Holland America Zaandam*, and *Celebrity Coral Princess*. The *Costa Magica* and the *Costa Favolosa*, reported at least 88 ill crew members on board with respiratory symptoms of COVID-19. On March 26, 2020, in coordination with U.S. Coast Guard and public health personnel, four infected crew members were evacuated off the *Magica* and seven from the *Favolosa* for life-critical care at Jackson Memorial Hospital in Miami, Florida. The *Zaandam* cruise ship reported illness consistent with COVID-19 in at least 250 persons onboard – guests and crew members; 76 of these persons remain symptomatic. Four passengers onboard the *Zaandam* have died (one for non-COVID-19 related reasons).⁶ As of April 1, 2020, four crew members onboard the *Eclipse* have tested positive for COVID-19, three of whom remain on the ship. One passenger onboard the *Eclipse* required emergency medical evacuation and is currently hospitalized in San Diego, California after having tested positive for COVID-19. The *Wonder* reported four crew members who have tested positive for COVID-19. Two of the four are now hospitalized, the two others are isolated on the ship; an additional three former passengers (from the last voyage who disembarked) are also positive. Most recently, the *Coral Princess* reported 12 persons (seven passengers and five crew members) onboard who are confirmed positive for COVID-19 and an additional 43 suspected cases in persons with influenza-like illness. As of April 3, 2020, there are four patients on oxygen in the ship's medical center.

There are approximately 50 cruise ships that remain at sea off the East Coast of the United States and in the Bahamas with an estimated 47,800 crew onboard; off the West Coast and Gulf Coast there are approximately 45 cruise ships with an estimated 32,000 crew onboard. Some of these crew are not critical to maintain the seaworthiness or basic safe operation of the cruise ships; many are part of the hotel and hospitality crew. CDC is currently aware of 15 cruise ships at port or anchorage in the United States with known or suspected COVID-19 infection among the crew who remain onboard. CDC is currently tracking two cruise ships with passengers that are expected to make port in the United States.

There are several public health concerns when crew members become ill while onboard these ships and the cruise lines seek the aid of the United States in disembarking them, as has already occurred on numerous occasions. The intensive care requirements for infected crew in need of life-critical care greatly stresses an already overburdened healthcare system facing shortages of masks, test kits, beds, and ventilators needed to respond to COVID-19. The addition of further COVID-19 cases from cruise ships places healthcare workers at substantial increased risk. Moreover, safely evacuating, triaging, and repatriating cruise ship crew involves complex

⁶ “President of Holland America cruise line pleads for compassion while Florida debates allowing ships to dock,” Fox News, March 31, 2020, available at: <https://www.foxnews.com/travel/zaandam-holland-america-cruise-president-florida-debate>.

logistics, incurs financial costs at all levels of government, and diverts resources away from larger efforts to suppress or mitigate COVID-19.

Critical Need for Further Cooperation and Response Planning

CDC and other Federal agencies engaged with CLIA representatives in early March. On March 13, 2020, CLIA and their associated members announced that all member cruise lines would voluntarily suspend cruise ship operations from U.S. ports of call for 30 days as public health officials and the Federal government continue to address COVID-19. Several cruise lines followed CLIA's example and similarly voluntarily suspended operations.

CLIA also drafted a response plan, "On Course: Cruise Industry COVID-19 Response and Protocols" (hereinafter, "On Course"). The plan proposed "industry management of suspected or confirmed cases of COVID-19 without burden on the U.S. government."⁷ CLIA stated that it could implement this plan within 7 days.⁸ In response to a suspected or confirmed case of COVID-19, "industry would be responsible for transporting the [exposed or infected] individuals in appropriate buses, cars, or ambulances."⁹ Furthermore, CLIA averred that, "contracts for predesignated facilities though Global Rescue [a firm with purported experience and expertise in mass medical incidents] [would] receive COVID-19 patients, including arrangements [that] will be executed following plan approval."¹⁰ CLIA further stated that it had planned for "multiple redundancies" in its response efforts. Specifically, "CLIA commits to making five ships available for temporary housing purposes. They would be tasked with sailing to any affected ship and taking affected guests and crew aboard for the self-isolation period."¹¹

On April 3, 2020, CLIA drafted a new response plan, "Framework: For Cruise Industry Care of Crew and other Persons on Board while Ships Remain Idle during the Global COVID-19 Pandemic" (hereinafter, "Framework"). The Framework plan must go further to reduce industry reliance on government and shoreside hospital resources. For example, while the Framework states that a ship will maintain its medical staff, it must provide further details of how the industry will provide for the acute care needs of the critically ill. The Framework must also address industry assistance to COVID-19 affected cruise ships by deploying additional ships for cohort separation of those who are exposed, infected, and in need of hospitalization. Furthermore, laboratory sampling and testing, onboard mitigation and prevention strategies, disinfection protocols, personal protective equipment, repatriation of foreign nationals, and onshore transportation, including through contract medivac helicopter, must be addressed in further detail, including how the industry proposes to acquire, staff, and operationalize this plan, with minimal burden on Federal, State, or local government entities or the healthcare system.

Findings and Immediate Action

⁷ (On Course, pages 1, 10).

⁸ *Id.* at 2.

⁹ *Id.* at 1-2.

¹⁰ *Id.* at 7.

¹¹ *Id.* at 13.

Accordingly, and consistent with 42 CFR §§ 70.2, 71.31(b) and 71.32(b), the Director of CDC (“Director”) finds that cruise ship travel exacerbates the global spread of COVID-19 and that the scope of this pandemic is inherently and necessarily a problem that is international and interstate in nature and has not been controlled sufficiently by the cruise ship industry or individual State or local health authorities. As described in the March 14, 2020 Order, cruise ship travel markedly increases the risk and impact of the COVID-19 disease outbreak within the United States. If unrestricted cruise ship passenger operations were permitted to resume, infected and exposed cruise ship cases would place healthcare workers at substantial increased risk. Specifically, these cases would divert medical resources away from persons with other medical problems and other COVID-19 cases, consuming precious diagnostics, therapeutics, and protective equipment. Ongoing concerns with cruise ship transmission would further draw valuable resources away from the immense Federal, State, and local effort to contain and mitigate the spread of COVID-19. Further, the current ongoing non-passenger operation of cruise ships has not sufficiently abated the public health concern, as ship crew become sick and require medical care drawing on otherwise engaged Federal, State, and local resources. As operators of non-U.S. flagged vessels sailing in international waters, it is imperative that the cruise ship industry and cruise lines themselves take responsibility for the care of their crew and do not further tax limited U.S. resources during a public health emergency.

The Director also finds evidence to support a reasonable belief that cruise ships are or may be infected or contaminated with a quarantinable communicable disease.¹² This reasonable belief is based on information from epidemiologic and other data regarding the nature and transmission of COVID-19 on cruise ships, including the information described in the March 14, 2020 Order and evidence from the *Costa Magica*, *Costa Favolosa*, *Eclipse*, *Wonder*, *Zaandam*, *Coral Princess*, and other cruise ships. As a result, persons onboard cruise ships may be infected with or exposed to COVID-19 by virtue of being onboard at a time when cases of COVID-19 are being reported in increasingly significant numbers globally¹³ and specifically on cruise ships, when testing is available.

Accordingly, under 42 CFR § 70.2, the Director determines that measures taken by State and local health authorities regarding COVID-19 onboard cruise ships are inadequate to prevent the further interstate spread of the disease.

This Order is not a rule within the meaning of the Administrative Procedure Act (“APA”), but rather an emergency action taken under the existing authority of 42 CFR §§ 70.2, 71.31(b) and 71.32(b). In the event that this Order qualifies as a rule under the APA, notice and comment and a delay in effective date are not required because there is good cause to dispense with prior public notice and comment and the opportunity to comment on this Order and the delay in effective date.¹⁴ Considering the public health emergency caused by COVID-19 based, among other things, on its continued spread on board cruise ships, it would be impracticable and

¹² COVID-19 is a communicable disease for which quarantine is authorized under Section 361 of the Public Health Service Act (42 U.S.C. § 264) and 42 CFR §§ 70.1, 71.1, as listed in Executive Order 13295, as amended by Executive Orders 13375 and 13674.

¹³ Since the March 14, 2020 Order, the number of global cases of COVID-19 reported by the World Health Organization (WHO) has risen from 142,534 to 1,051,635 as of April 4, 2020, with 56,985 deaths. See Situation Reports, WHO, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports>.

¹⁴ See 5 U.S.C. §§ 553(b)(B), (d)(3).

contrary to the public health, and by extension the public interest, to delay the issuance and effective date of this Order. Similarly, if this Order qualifies as a rule per the definition in the APA, the Office of Information and Regulatory Affairs has determined that it would be a major rule, but there would not be a delay in its effectiveness as the agency has invoked the good cause provision of the APA.

If any provision in this Order, or the application of any provision to any carriers, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, persons or circumstances other than those to which it is held invalid, shall remain valid and in effect.

In accordance with 42 U.S.C. § 264(e), this Order shall supersede any provision under State law (including regulations and provisions established by political subdivisions of States), that conflict with an exercise of Federal authority, including instructions by U.S. Coast Guard (USCG) or HHS/CDC personnel permitting ships to make port or disembark persons under stipulated conditions, under this Order.

This Order shall be enforceable through the provisions of 18 U.S.C. §§ 3559, 3571; 42 U.S.C. §§ 243, 268, 271; and 42 CFR §§ 70.18, 71.2.

Therefore, in accordance with Sections 361 and 365 of the Public Health Service Act (42 U.S.C. §§ 264, 268) and 42 CFR §§ 70.2, 71.31(b), 71.32(b), for all cruise ships for the period described below, it is **ORDERED**:

1. As a condition of obtaining controlled free pratique to continue to engage in any cruise ship operations in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, cruise ship operators shall immediately develop, implement, and within **seven (7) days** of the signing of this Order operationalize, an appropriate, actionable, and robust plan to prevent, mitigate, and respond to the spread of COVID-19 on board cruise ships.
2. As a condition of obtaining controlled free pratique to continue to engage in any cruise ship operations in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, the cruise ship operator shall make the plan described in paragraph 1, above, available to HHS/CDC and USCG personnel within **seven (7) days** of the signing of this Order.
3. An appropriate plan is one that adequately prevents, mitigates, and responds to the spread of COVID-19 on board cruise ships and that, at a minimum, must address the following elements:
 - a. Onboard surveillance of passengers and crew with acute respiratory illnesses, influenza-like illnesses, pneumonia, and COVID-19, including reporting to HHS/CDC on a weekly basis on overall case counts, methods of testing, and number of persons requiring hospitalization or medical evacuation;
 - b. Reports on the number of persons onboard the cruise ship and any increase in the numbers of persons with COVID-19 made to HHS/CDC and USCG on a daily

basis for as long as the cruise ship is within waters subject to the jurisdiction of the United States.

- c. Onboard monitoring of passengers and crew through temperature checks and medical screening, including addressing frequency of monitoring and screening;
- d. Training of all crew on COVID-19 prevention, mitigation, and response activities;
- e. Protocols for any COVID-19 testing, including details relating to the shore-side transport, administration, and operationalization of laboratory work if onboard laboratory work is not feasible;
- f. Onboard isolation, quarantine, and social distancing protocols to minimize the risk of transmission and spread of COVID-19;
- g. Onboard medical staffing, including number and type of staff, and equipment in sufficient quantity to provide a hospital level of care (e.g., ventilators, facemasks, personal protective equipment) for the infected without the need for hospitalization onshore;
- h. An outbreak management and response plan to provision and assist an affected cruise ship that relies on industry resources, e.g., mobilization of additional cruise ships or other vessels to act as “hospital” ship for the infected, “quarantine” ship for the exposed, and “residential” ship for those providing care and treatment, including the ability to transport individuals between ships as needed;
- i. Categorization of affected individuals into risk categories with clear stepwise approaches for care and management of each category;
- j. A medical care plan addressing onboard care versus evacuation to on-shore hospitals for critically ill individuals, specifying how availability of beds for critically ill at local hospitals will be determined in advance and how the cruise ship operator will ensure acceptance at local medical facilities to treat the critically ill in a manner that limits the burden on Federal, State, and local resources and avoids, to the greatest extent possible, medivac situations. If medical evacuation is necessary arrangements for evacuation must be made with commercial resources (e.g., ship tender, chartered standby vessel, chartered airlift) and arrangements made with a designated medical facility that has agreed to accept such evacuees. All medical evacuation plans must be coordinated with the U.S. Coast Guard;
- k. Detailed logistical planning for evacuating and repatriating, both U.S. citizens and foreign nationals, to their respective communities and home countries via foreign government or industry-chartered private transport and flights, including the steps the cruise ship operator will take to ensure those involved in the transport are not exposed; (the use of commercial flights to evacuate or repatriate individuals, both within or from the United States, is prohibited);
- l. The projected logistical and resource impact on State and local government and public health authorities and steps taken to minimize the impact and engage with these authorities; all plans must provide for industry/cruise line management of suspected or confirmed cases of COVID-19 without resource burden on Federal, State, or local governments;
- m. Plan execution in all U.S. geographical areas – all plans must be capable of being executed anywhere in international, interstate, or intrastate waterways subject to the jurisdiction of the United States; and

- n. Cleaning and disinfection protocols for affected cruise ships.
4. An appropriate plan shall be designed to minimize, to the greatest extent possible, any impact on U.S. government operations or the operations of any State or local government, or the U.S. healthcare system.
5. The cruise ship operator shall further ensure that the plan is consistent with the most current CDC recommendations and guidance for any public health actions related to COVID-19. Where appropriate, a cruise ship operator may coordinate the development, implementation, and operationalization of a plan with other cruise ship operators, including an industry trade group.

The terms and conditions of the No Sail Order and Other Measures Related to Operations signed on March 14, 2020, as modified and extended by this ORDER, **SHALL REMAIN IN EFFECT**. Consequently, it remains **ORDERED**:

1. Cruise ship operators shall not be allowed to disembark passengers and crew members at ports or stations, except as directed by the USCG, in consultation with HHS/CDC personnel and, as appropriate, as coordinated with Federal, State, and local authorities.
2. Cruise ship operators shall not reembark any crew member, except as approved by USCG, in consultation with HHS/CDC personnel, until further notice.
3. Cruise ship operators shall not embark any new passengers or crew, except as approved by USCG, or other Federal authorities as appropriate, in consultation with HHS/CDC personnel.
4. Cruise ship operators shall not commence or continue operations (e.g., shifting berths, moving to anchor, or discharging waste), except as approved by USCG, in consultation with HHS/CDC personnel, until further notice.
5. While in port, the cruise ship operator shall observe health precautions as directed by HHS/CDC personnel.
6. The cruise ship operator shall comply with all HHS/CDC, USCG, and other Federal agency instructions to follow CDC recommendations and guidance for any public health actions relating to passengers, crew, ship, or any article or thing on board the ship, as needed, including by making ship's manifests and logs available and collecting any specimens for COVID-19 testing.
7. This order does not prevent the periodic reboarding of the ship by HHS/CDC personnel and/or USCG and/or other Federal, State, or local agencies or the taking on of ships' stores and provisions under the supervision of HHS/CDC personnel and/or USCG.

8. This order does not prevent the ship from taking actions necessary to maintain the seaworthiness or safety of the ship, or the safety of harbor conditions, such as movement to establish safe anchorage, or as otherwise directed by USCG personnel.

This Order is effective upon publication in the Federal Register and shall continue in operation until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID-19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the order based on specific public health or other considerations; or (3) 100 days from the date of publication in the Federal Register.

In testimony whereof, the Director, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, has hereunto set his hand at Washington, D.C., this 9th day of April, 2020.

A handwritten signature in black ink that reads "Robert R. Redfield MD". The signature is written in a cursive, flowing style.

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention

EXHIBIT 4

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)**

**ORDER UNDER SECTIONS 361 & 365
OF THE PUBLIC HEALTH SERVICE ACT (42 U.S.C. 264, 268) AND
42 CODE OF FEDERAL REGULATIONS
PART 70 (INTERSTATE) AND PART 71 (FOREIGN):**

**SECOND MODIFICATION AND EXTENSION OF NO SAIL ORDER
AND OTHER MEASURES RELATED TO OPERATIONS**

Executive Summary

The coronavirus disease 2019 (COVID-19) pandemic continues to spread rapidly around the world with no treatment or vaccine, with over 12.5 million confirmed cases and over 560,000 confirmed deaths worldwide as of July 12, 2020. On July 12, 2020, 230,000 new COVID-19 cases were reported, the largest single-day tally worldwide since the epidemic began. It took 3 months to reach the first million cases of COVID-19, but during one week in June 2020, 1 million new cases were reported worldwide.

Since HHS/CDC's original No Sail Order, signed on March 14, 2020, which restricted the embarkation of passengers, CDC has worked to control COVID-19 on cruise ships that remained at sea, while protecting against further introduction and spread of COVID-19 into U.S. communities. As of July 10, 2020, CDC has expended an estimated 38,000 person-hours on the cruise ship COVID-19 response since March 14, 2020—in addition to the thousands of hours invested by other HHS components, other U.S. government agencies, and state and local authorities. CDC continues to have regular conversations by phone and email with cruise lines, often daily.

Cumulative CDC data from the period of March 1 to July 10, 2020 reveal a total of 2,973 COVID-19 or COVID-like illness cases on cruise ships, in addition to 34 deaths. These data have also revealed a total of 99 outbreaks on 123 different cruise ships, meaning that 80% of ships within U.S. jurisdiction were affected by COVID-19 during this time frame. In addition, 9 ships still have ongoing or resolving COVID-19 outbreaks on board.

The challenges described in this document highlight the need for further action prior to cruise ships' resuming passenger operations. CDC supports the decision by the Cruise Line International Association (CLIA) and its members to voluntarily extend the suspension of operations for passenger cruise ship travel. However, because not all cruise ship operators subject to the No Sail Order are members of CLIA or have made similar commitments, CDC is extending its No Sail Order to ensure that passenger operations do not resume prematurely.

Previous Orders and Incorporation by Reference

This Order renews the No Sail Order and Other Measures Related to Operations signed by the CDC Director on March 14, 2020,¹ as further modified and extended effective April 15, 2020²—subject to the modifications and additional stipulated conditions as set forth in this Order.

This Order shall remain in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID-19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the Order based on specific public health or other considerations; or (3) September 30, 2020.

The findings and other evidence relied upon in issuing the March 14 and April 15, 2020 Orders are incorporated herein by reference. Any ambiguity between the March 14, and April 15, 2020 Orders, as modified by the current Order, shall be resolved in favor of the current Order.

Statement of Intent

This Order shall be interpreted and implemented in a manner as to achieve the following paramount objectives:

- Preserving human life;
- Preserving the health and safety of cruise ship crew members, port personnel, and communities;
- Preventing the further introduction, transmission, and spread of COVID-19 into and throughout the United States;
- Preserving the public health and other critical resources of Federal, State, and local governments;
- Preserving hospital, healthcare, and emergency response resources within the United States; and
- Maintaining the safety of shipping and harbor conditions.

Applicability

This Modification and Extension of No Sail Order and Other Measures Related to Operations shall apply only to the subset of carriers³ described below and hereinafter referred to as “cruise ships”:

¹ No Sail Order and Suspension of Further Embarkation. www.federalregister.gov/documents/2020/03/24/2020-06166/no-sail-order-and-suspension-of-further-embarkation. Last accessed June 24, 2020.

² No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations. www.federalregister.gov/documents/2020/04/15/2020-07930/no-sail-order-and-suspension-of-further-embarkation-notice-of-modification-and-extension-and-other. Last accessed June 24, 2020.

³ Carrier is defined by 42 CFR § 71.1 to mean, “a ship, aircraft, train, road vehicle, or other means of transport, including military.”

All commercial, non-cargo,⁴ passenger-carrying vessels with the capacity⁵ to carry 250⁶ or more individuals (passengers and crew) and with an itinerary anticipating an overnight stay onboard or a twenty-four (24) hour stay onboard for either passengers or crew that are operating in international, interstate, or intrastate waterways, subject to the jurisdiction of the United States.⁷

This Order shall additionally apply to cruise ships operating outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in international, interstate, or intrastate waterways, subject to the jurisdiction of the United States during the period that this Order is in effect.

Definitions

The following definitions shall apply for the purposes of this Order:

COVID-19 means the disease caused by the coronavirus SARS-CoV-2.

“Operations,” “Operate,” and “Operating” means any action by a cruise ship operator (e.g., shifting berths, moving to anchor, discharging waste, making port, or embarking or disembarking passengers or crew) to bring or cause a cruise ship to be brought into or transit in or between any international, interstate, or intrastate waterways, or maintaining a ship in layup status,⁸ subject to the jurisdiction of the United States.

“Operator” means the Master of the vessel (cruise ship) and any other crew member responsible for cruise ship operations and navigation, as well as any person or entity (including a corporate entity) that authorizes or directs the use of a cruise ship (e.g., as owner, lessee, or otherwise). A cruise ship operator may be either the cruise ship captain or the cruise line to which the cruise ship belongs, or both. The term “Operator” as used in this Order further incorporates the terms “company,” “designated person,” and “responsible person” as defined in 33 CFR. § 96.120.

⁴ Given the substantial risk of person-to-person transmission of COVID-19, as opposed to transmission via indirect contact, this Order is currently limited to passenger, non-cargo vessels.

⁵ A ship’s capacity shall be determined based on the number of persons listed in the U.S. Coast Guard Certificate of Inspection issued in accordance with 46 CFR § 2.01-5 and that was in effect on the date of the signing of this current Order.

⁶ Based on substantial epidemiologic evidence related to congregate settings and mass gatherings, this Order suspends operation of vessels with the capacity to carry 250 individuals or more. Evidence shows that settings as small as nursing homes or movie theaters can proliferate the spread of a communicable disease. As the numbers of passengers and crew on board a ship increase, certain recommended mitigation efforts such as social distancing become more difficult to implement. In light of the demonstrated rapid spread of COVID-19 in cruise ship settings, application of this Order to vessels carrying 250 or more individuals is a prudent and warranted public health measure. Moreover, during the early part of 2020, management of COVID-19 cases in addition to care needs resulting from the seasonal influenza epidemic placed an extreme burden on public health and healthcare systems and this Order will help avoid further stressing those systems.

⁷ This order shall not apply to vessels operated by a U.S. Federal or State government agency. Nor shall it apply to vessels being operated solely for purposes of the provision of essential services, such as the provision of medical care, emergency response, activities related to public health and welfare, or government services, such as food, water, and electricity.

⁸ Layup means reducing cruise ship operations to those levels needed to maintain essential machinery and equipment so that the ship may be returned to service.

Events Necessitating the March 14 and April 15, 2020 Orders

On January 20, 2020, the *Diamond Princess* cruise ship departed Yokohama, Japan. On January 25, 2020, a symptomatic passenger departed the ship in Hong Kong, where he was later confirmed to have COVID-19. Upon the ship's return to Yokohama, Japanese authorities quarantined all passengers and crew on board the ship. Among the 3,711 *Diamond Princess* passengers and crew, 712 (19.2%) were subsequently confirmed to have COVID-19, 37 required intensive care, and nine died. Following this outbreak, two voyages of the *Grand Princess* cruise ship were ultimately associated with 159 confirmed COVID-19 cases, including eight deaths.⁹

Because of these events, and the increased risk of transmission on cruise ships, on March 14, 2020, the CDC Director issued a No Sail Order and Other Measures Related to Operations directing cruise ships not voluntarily suspending operations to comply with certain measures. This followed a March 13, 2020, announcement by CLIA, the leading industry trade group, that its members would voluntarily suspend cruise ship operations. On March 17, 2020, CDC issued a Level 3 Travel Health Notice warning all travelers to defer cruise travel worldwide based on widespread ongoing transmission of COVID-19.¹⁰ Despite the announcement by CLIA, the application of the March 14, 2020 Order, and the Level 3 Travel Health Notice, cruise ships continued to be associated with COVID-19 outbreaks. Between March 14 and April 15, 2020, COVID-19 outbreaks were reported on several additional cruise ships. These included the Costa Cruises ships *Costa Magica* and *Costa Favolosa*; Holland America Line's *Zaandam*; the *Celebrity Eclipse*; the *Disney Wonder*; and Princess Cruises' *Coral Princess*.

COVID-19 outbreaks on cruise ships required 27 notifications by CDC to international, state, and local health departments for over 11,000 cruise ship passengers requiring contact tracing, which resulted in countless hours of work for numerous already-burdened public health officials. This number exceeded that of the number of contacts identified from flight investigations since the beginning of the pandemic. Medical evacuation efforts necessitated by these outbreaks required resource intensive operations that involved multiple small boats to ferry contagious crew to shore and high levels of coordination between Federal, State, and local public health, maritime, and other governmental authorities. Response efforts drew valuable resources away from the immense Federal, State, and local efforts to contain and mitigate the spread of COVID-19. State and local public health officials further stated that they faced an increasing burden supporting cruise ships attempting to make port with ill passengers or crew and struggled to repatriate passengers and crew while also protecting the limited medical assets available to their communities. The intensive care requirements for infected passengers and crew in need of life-saving critical care also greatly stressed an already overtaxed healthcare system that at the time was facing shortages of masks, test kits, beds, and ventilators needed to respond to COVID-19.

⁹ Moriarty LF, Plucinski MM, Marston BJ, et al. Public Health Responses to COVID-19 Outbreaks on Cruise Ships — Worldwide, February–March 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:347-352. <https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e3.htm>. Last accessed June 25, 2020.

¹⁰ CDC Travel Health Notice, *COVID-19 and Cruise Ship Travel*, at: <https://wwwnc.cdc.gov/travel/notices/warning/coronavirus-cruise-ship> (originally posted, March 17, 2020). Last accessed June 25, 2020.

Accordingly, to protect public health and safety and prevent the further introduction, transmission, and spread of COVID-19 into and throughout the United States, the CDC Director issued an Order modifying and extending the previous March 14, 2020 Order, which became effective on April 15, 2020.

Events Since the Issuance of the April 15, 2020 Extension

Under the April 15, 2020 Extension, as a condition of obtaining controlled free pratique to continue to engage in cruise ship operations in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, cruise ship operations were limited, and cruise lines were required to submit plans to prevent, mitigate, and respond to the spread of COVID-19 on board to ensure a safe work environment and disembarkation for crew members. The No Sail Order (NSO) response plans had to minimize to the greatest extent possible any impact on U.S. government operations or the operations of any State or local government, or the U.S. healthcare system. While working with cruise ship operators to ensure the completeness and accuracy of these response plans, CDC allowed crew members to disembark from cruise ships in U.S. waters and return home if cruise ship operators attested to complying with requirements to disembark crew members in such a manner as to minimize the risk to other travelers and communities. Among other requirements, safe disembarkation meant not using commercial transport for disembarking crew, screening disembarking crew members for illness, ensuring that crew members with known exposure to COVID-19 traveled separately from those with no known exposure, providing face masks or cloth face coverings to disembarking crew members or confirming that they had their own face coverings, and instructing disembarking crew members to stay home for 14 days and continue to practice social distancing after reaching their final destination. This disembarkation process proved cumbersome and labor intensive; it is still ongoing even now with over 14,000 crew remaining onboard, due in part to limited charter flight availability, cruise lines' cost burdens, and some destination countries' refusing to accept returning crew.

Following the April 15, 2020 Extension, CDC published its *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew During the Period of the No Sail Order* to assist cruise ship operators in preventing, detecting, and medically managing confirmed and suspected SARS-CoV-2 infections and exposures among crew members.¹¹ During this period, CDC also further assisted cruise ship operators with humanitarian medical evacuations for people in need of lifesaving support. As of July 10, 2020, CDC has worked with cruise ship operators to assist in the disembarkation and safe return home of approximately 8,825 crew members, including 314 U.S. citizens and residents.

Under the April 15, 2020 Extension, CDC established an enhanced surveillance process to provide a more complete picture of COVID-19 activity on cruise ships. CDC required weekly submission of the "Enhanced Data Collection (EDC) During COVID-19 Pandemic Form." The EDC form was used to conduct surveillance for COVID-19 among crew who remained on board

¹¹ CDC, *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew During the Period of the No Sail Order* at: <https://www.cdc.gov/quarantine/cruise/management/interim-guidance-no-sail-order.html>

cruise ships based on cumulative reports of acute respiratory illness (ARI),¹² influenza-like illness (ILI),¹³ pneumonia, and other clinical indicators. As of July 10, 2020, EDC reports have shown a total of 4,590 polymerase chain reaction (PCR) tests performed, 281 (6%) of which were positive, 18 hospitalizations, 2 instances of mechanical ventilation, and 9 medical evacuations for crew on ships within U.S. jurisdiction since April 15, 2020. CDC recommended that ships' surveillance include routine testing for SARS-CoV-2 infection, including intermittent testing of a random sample of symptomatic and asymptomatic crew members.

In addition to reviewing the NSO response plans, CDC continued to update its *Interim Guidance* as new information became available; provided technical expertise to ships with ongoing outbreaks; created cruise ship-specific websites to inform crew members, the public, and partners; and reviewed hundreds of attestations for safe disembarkation and transfer of crew members.

CDC also established a "COVID-19 Color Coding System" for ships applicable to cruise ship operators with an appropriate NSO response plan for crew management. Classification of ships under this system requires cruise company officials to sign an acknowledgment of the completeness and accuracy of their NSO response plans upon completion of CDC review of the plan. CDC additionally provides a provisional color status for ships belonging to cruise lines that do not yet have a complete and accurate plan. CDC assesses the status of a ship by reviewing surveillance data from the weekly EDC form.

- "Green" ship status means that a ship has no confirmed cases of COVID-19 or COVID-like illness for 28¹⁴ consecutive days among crew members onboard. In addition, cruise ship operators must sign an attestation that if the ship received ship-to-ship transfers, the crew members came from a ship with no cases of COVID-19 or COVID-like illness within the 28 days before the transfer occurred and that land-based crew embarking the ship were immediately quarantined for 14 days. Ships achieving "Green" status may use commercial travel to disembark crew members and may lessen onboard restrictions to allow crew to resume some daily interactions with fellow crew members, including social gatherings, group meetings, and use of group settings such as crew bars and gyms.
- "Yellow" ship status means that a previously designated "Green" ship reported one or more COVID-like illness cases onboard and that testing for COVID-19 is pending. If crew with COVID-like illness are not tested by PCR or if results are not available within 1 week of the case being reported, then the ship's status changes to "Red." Ships with a "Yellow" status are required to resume all preventive measures, with the exception of requiring crew members to remain in cabins as much as possible during non-working hours, and are no longer eligible for commercial travel of disembarking crew.

¹² Acute Respiratory Illness (ARI) is defined as the presence of cough, sore throat, or rhinorrhea in the absence of fever.

¹³ Influenza-like Illness (ILI) is defined as fever (100.4 °F [38 °C]) plus either cough or sore throat in the absence of another diagnosis.

¹⁴ The 28-day period for COVID-19 is based on the public health standard of 2 incubation periods, which is commonly used to determine that a communicable disease of public health concern is no longer circulating in a location.

- “Red” ship status means that one or more cases of laboratory-confirmed COVID-19 or COVID-like illness have occurred onboard within the past 28 days, that ship-to-ship transfers occurred from a ship that was not “Green,” that embarking crew were not immediately quarantined for 14 days, or that the ship failed to submit one or more weekly EDC forms during the past 28 days. Ships with a “Red” status must follow all preventive measures, including requiring crew members to remain in cabins as much as possible during non-working hours, until the ship’s status changes to “Green.”

The status of the cruise ship operator NSO response plans and the color-coding status for individual ships are updated weekly at <https://www.cdc.gov/coronavirus/2019-ncov/travelers/crew-disembarkations-commercial-travel.html>.

Difficulty of Cruise Ship Operators in Submitting Appropriate Response Plans

As of April 29, 2020, CDC had received NSO response plans from seven cruise ship operators representing approximately 110 cruise ships or about 95% of cruise ships subject to the April 15, 2020 Extension. These operators included Carnival Corporation,¹⁵ Royal Caribbean Cruise Line, Norwegian Cruise Lines, Disney Cruise Lines, Virgin Voyages, Windstar Cruises,¹⁶ and Bahamas Paradise Cruise Lines. MSC Cruises submitted an NSO response plan on May 7, 2020, covering three of its ships.

In order to manage the public health crisis occurring at sea, including analyzing epidemiologic data, reviewing and responding to NSO response plan submissions, and managing the safe disembarkation of crew, CDC created a Maritime Unit (MU) staffed with 30 subject matter experts. The MU developed an email box staffed 7 days a week to handle the volume of cruise-related inquires received by CDC during the pandemic and established daily communications with cruise lines. For the plan review process, two MU team members were assigned to review each plan and communicate with the submitting cruise line. The work-intensive plan review process has involved assessing hundreds of documents from each cruise line to determine if they completely and adequately addressed the elements of an appropriate plan described in the April 15, 2020 Extension. Most plans needed two complete reviews and revisions, with one plan requiring seven rounds of revisions.

The plans as initially submitted by the cruise lines were incomplete and did not fully meet all the requirements of the April 15, 2020 Extension. Areas of major concern included insufficient details for monitoring crew onboard; unspecified quantities of personal protective equipment, medical and laboratory supplies, and fever-reducing medications; incomplete plans to disembark asymptomatic crew safely; missing shoreside and onboard testing agreements, supplies, and protocols; not isolating symptomatic crew; failing to close self-service buffets, salons, gyms, and

¹⁵ On May 24 and again on June 3, 2020, Carnival Corporation communicated to CDC that none of its operating companies had any ships in U.S. waters, nor did they expect to have any ships returning to U.S. waters before the end of the NSO period. Accordingly, CDC has held its review of the Carnival response plan in abeyance.

¹⁶ While Windstar Cruises initially submitted an NSO response plan for one of its ships, it later withdrew its ships from U.S. waters and stated it had no intention of returning those ships to U.S. waters during the period of the NSO. Accordingly, CDC has held its review of the Windstar response plan in abeyance.

recreational water facilities; lack of ability to provide the required level of medical care; and implementing social distancing and other restrictions only when physically present in U.S. waters. CDC has provided feedback to assist cruise lines in determining how best to address these concerns.

By July 10, 2020, cruise ship operators had reduced the number of cruise ships they proposed to operate in U.S. waters to approximately 49 ships, with some operators choosing to temporarily withdraw all ships remaining in U.S. waters. As of July 10, 2020, one cruise ship operator representing only one cruise ship operating in U.S. waters had an NSO response plan meeting all the elements described in the April 15, 2020 Extension: Bahamas Paradise Cruise Line.

Examples of Potential Non-Compliance with the Extended No Sail Order

The difficulty of cruise ship operators in submitting appropriate NSO response plans was compounded by several instances of potential non-compliance with the requirements of the April 15, 2020 Extension. On April 29, 2020, CDC sent a Notice of Potential Non-Compliance with the No Sail Order to Holland America Line in response to attempts by a crew member to disembark from the *Oosterdam* without cruise line officials' attesting that precautions to protect public health had been taken. This attempted disembarkation without appropriate precautions required CDC, U.S. Coast Guard, U.S. Customs and Border Protection, California Department of Public Health, Los Angeles County Health Department, and Los Angeles Police Department to leverage valuable resources and work together to enforce the NSO. In response, Holland America Line stated that the incident was the result of confusion between *Oosterdam* administrative personnel and local port agents. As a corrective measure, Holland America Line spoke to the local agents at the Port of Los Angeles and instructed them not to approve further disembarkations unless specifically instructed by shoreside management.

On May 11, 2020, CDC sent a "Dear Colleague" letter to cruise ship operators. The letter stated that CDC was aware of allegations of cruise ship non-compliance with the April 15, 2020 Extension through social media and other sources. Alleged instances of non-compliance included not adhering to social distancing protocols; unauthorized crew transfers while outside of U.S. waters; not submitting weekly surveillance data (through the EDC form); not relocating all crew to single-occupancy cabins with private bathrooms; not cancelling all social gatherings; and not closing all crew bars, gyms, or other group settings. The letter requested that cruise ship operators investigate and report instances of non-compliance to CDC and explain in writing what corrective actions had been taken to ensure future compliance. Only two cruise ship operators, Virgin Voyages¹⁷ and Royal Caribbean Cruise Ltd (RCL), and CLIA¹⁸ responded in writing.

¹⁷ On May 13, 2020, Virgin Voyages submitted a report listing non-conformities with the NSO. As a corrective measure, it added its NSO response plan in its entirety to its company Safety Management System and further advised its ships that any proposed deviations required advance approval.

¹⁸ On May 14, 2020, CLIA responded to the letter requesting a meeting with the CDC Director to further engage with CDC. Subsequently, on June 11, the CDC Director hosted a teleconference with CLIA and other members of the cruise line industry during which CDC responded to questions submitted by CLIA relating to procedures, clarifications, and crew transfers and repatriations under the NSO.

On May 13, 2020, RCL responded to the May 11 “Dear Colleague” letter stating that it had investigated the allegations in the six areas described in the letter and believed that it was in full compliance. On June 9, 2020, CDC sent a letter to RCL stating that on May 20, 2020, CDC had received attestations for 64 ship-to-ship transfers occurring from May 12 to May 20 for 21 ships in both the Royal Caribbean International and Celebrity Cruises, Inc. brands. While RCL had originally represented that these transfers were for crew who met CDC’s criteria for “recovered” from COVID-19, RCL in later communications acknowledged that transferred crew had not met these criteria. Furthermore, while RCL officials did submit multiple attestations for these transfers, the attestations were submitted belatedly after the transfers were complete. The submitted attestations were also per ship, not per disembarkation, and lacked a required disembarkation date. For these reasons, the attestations were inconsistent with CDC’s *Interim Guidance*. On June 15, 2020, RCL responded stating that these incidents were due to a misinterpretation of the *Interim Guidance* and that it would adjust its practices in the future.

On May 22, 2020, CDC sent a Notice of Potential Non-Compliance with the No Sail Order to Norwegian Cruise Line Holdings Ltd (NCLH). The notice stated that CDC had become aware of reports of alleged non-compliance on several NCLH cruise ships including the *Norwegian Escape*, *Norwegian Epic*, *Norwegian Joy*, *Oceania Marina*, and *Seven Seas Navigator*. These allegations included not adhering to social distancing protocols, not cancelling all social gatherings, not relocating all crew to single-occupancy cabins with private bathrooms, not suspending self-service buffets, and crew not wearing cloth face coverings when outside individual cabins. CDC further requested that NCLH address the veracity of these allegations and outline what corrective steps it would take to prevent reoccurrences.

On May 29, 2020, NCLH sent a response to CDC’s May 22 letter. It cited the difficulty in achieving and mandating social distancing among crew members at all times. NCLH had modified dining venues, seating, and meal service to facilitate social distancing, but allowed a “maximum of 4 persons at a table” onboard all ships. It had also “designated large open-air area spaces to be utilized by crew at their leisure, limiting the amount of people and encouraging social distancing.” NCLH stated that ships operating with reduced manning limited its ability to operate without self-service buffets. Lastly, NCLH stated that it believed it had exceeded CDC’s guidance “by not just asking but encouraging our crew to wear face coverings.” NCLH’s response did not specifically address what corrective actions it would take to align its practices with CDC’s *Interim Guidance* and did not address the issue of not relocating crew to single-occupancy cabins with private bathrooms.

On July 2, 2020, CDC sent NCLH an additional notice requesting that it take immediate corrective action to align its practices with the April 15, 2020 Extension and CDC’s *Interim Guidance*. CDC asked NCLH to explain with greater specificity what steps it had taken to instruct crew across its fleet to wear cloth face coverings when outside of individual cabins (e.g., through posted signage or verbal reminders). CDC further noted that depending on table size, allowing a maximum of 4 persons at a table did not ensure maintaining a minimum distance of 2 meters (6 feet) from one another during meal service. Furthermore, to the extent that NCLH had allowed crew to gather in any group setting, it was advised to discontinue this practice until “Green” status onboard the ship had been achieved. Moreover, CDC advised NCLH that operating a self-service meal operation was considered a high-risk practice because of the role of

fomites in transmission of COVID-19 and advised it to discontinue this practice on all ships across its fleet. Lastly, CDC requested NCLH explain whether it had at any time not relocated all crew to single-occupancy cabins with private bathrooms.

On July 9, 2020, CDC received NCLH's response to its July 2 letter. NCLH stated that it had implemented new procedures to mandate the wearing of face coverings by crew members when outside of individual cabins. To reinforce this mandate, it had instituted "mask patrols" comprised of security team members who were authorized to order crew members back to their cabins if seen not properly masked in public areas. NCLH also confirmed that it had discontinued its previous practice of allowing up to four crewmembers to dine together at the same table. It further confirmed that it understood CDC's color-coding system and noted that all gyms, bars, and lounges fleetwide were closed and remained closed since the inception of the NSO. NCLH had also disseminated CDC materials in written form fleetwide to all crew members, instead of conducting in person meetings or trainings on COVID-19. NCLH further confirmed that it had discontinued self-service meal operations and in lieu of such self-service operations had designated crew members to assist other crew members during meal service. Lastly, while it had initially found housing of all crew members in single-occupancy cabins to be infeasible based on the number of crew members on board, it confirmed that all remaining crew members who had not repatriated were currently housed in single occupancy cabins with private bathrooms.

On June 10, 2020, CDC sent a Notice of Potential Non-Compliance with the No Sail Order to Disney Cruise Lines (DCL) relating to inadequate spacing and mixing of staterooms intended for "well" and "sick" crew and potential failure to discontinue buffet meal service during an ongoing COVID-19 outbreak. These concerns were based on records and photographs received by CDC from the *Disney Wonder* to document compliance with elements outlined in the April 15, 2020 Extension. CDC also sent DCL a separate letter documenting its concerns regarding a sustained outbreak of COVID-19 or COVID-like illness among crew onboard the *Disney Wonder* during the period of the April 15, 2020 Extension. Since April 15, 2020, CDC had received reports of 181 cases of confirmed COVID-19 and 19 case of COVID-like illness associated with this ship. Of particular concern was the fact that this outbreak had continued over a ten-week time frame, including before the April 15, 2020 Extension, with the last date of COVID-like illness reported to CDC on May 25, 2020.

On June 24, 2020, DCL responded that inadequate spacing and mixing of staterooms intended for "well" and "sick" crew occurred because of the challenges of transferring asymptomatic, symptomatic, and COVID-19-positive crew members between rooms and limited availability of vacant staterooms with balconies. DCL also denied that an "active" buffet meal service was in place and affirmed that crew members would point out desired meal items and then have other crew members serve those items to them on a plate. In regard to the outbreak onboard the *Disney Wonder*, DCL asserted that any discrepancies in reporting positive test results to the CDC were due to inadvertent error. As a corrective action, DCL stated that it had reviewed and reinforced the proper procedures for reporting of illness to the CDC. In describing what factors may have led to the magnitude and duration of this outbreak, DCL noted that numerous crew members who subsequently tested positive for COVID-19 were asymptomatic and that some of these crew

members served as essential crew and were not quarantined in their rooms until the results of ship-wide testing were received.

Actions Taken by Other Countries in Regard to Cruise Ship Travel

A number of countries have taken aggressive steps to mitigate the risks of COVID-19 exacerbated by cruise ship travel. On March 9, 2020, Canada's Chief Public Health Officer issued a formal health advisory asking all Canadians to avoid travelling on cruise ships because the ships represent a high-risk environment for viral transmission of COVID-19. On March 19, 2020, the Canadian Government issued Ship Safety Bulletin No. 05/2020: *Deferral of the Canadian Cruise Ship Season for Vessels Capable of Carrying 500 Persons or More until July 1, 2020*.¹⁹ These regulations restricted cruise ships capable of carrying 500 or more persons, including both passengers and crew members from accessing ports managed by port authorities, public ports, public port facilities, and the St. Lawrence Seaway until July 1, 2020. On May 29, 2020, these restrictions were extended to cruise ships with overnight accommodations carrying more than 100 people operating in Canadian waters until October 31, 2020.

On March 18, 2020, the Governor-General of the Commonwealth of Australia declared a human biosecurity emergency that included a ban on international cruise ships entering Australian ports.²⁰ On May 15, 2020, the Governor-General extended the human biosecurity emergency period for an additional three months, from June 17 to September 17, 2020.²¹ This enabled the Minister for Health on May 20, 2020, to extend a prohibition on the arrival at any Australian port of any international cruise ship that had left a foreign port. These restrictions include direct arrivals and round-trip cruises. On May 22, 2020, the restriction on cruise ships entering Australian waters was extended for a further three months until September 17, 2020. Under this restriction, any cruise ship capable of carrying more than 100 passengers is prohibited from operating cruises in Australia. When this restriction went into effect on March 27, 2020, there were 28 international cruise ships in Australian waters. Under the direction of the Australian Border Force, these ships and their crew safely departed.

In addition, as of July 10, 2020, numerous countries have restricted passenger cruise ship travel to some degree. These include Aruba, Barbados, Bermuda, British Virgin Islands, Cayman Islands, Dominican Republic, Greece, Grenada, Honduras, Norway, Panama, Seychelles, and Spain.

Supplemental Information Relating to COVID-19 Transmission Onboard Cruise Ships

¹⁹ Deferral of the Canadian Cruise Ship Season for Vessels Capable of Carrying 500 Persons or More until July 1, 2020 - SSB No.: 05/2020. www.tc.gc.ca/eng/marinesafety/bulletins-2020-05-eng.htm. Last accessed June 24, 2020.

²⁰ COVID-19 Legislative response—Human Biosecurity Emergency Declaration Explainer. www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/FlagPost/2020/March/COVID-19_Biosecurity_Emergency_Declaration. Last accessed June 24, 2020.

²¹ Cruise Ship Prohibition Extended. www.newsroom.abf.gov.au/releases/cruise-ship-prohibition-extended. Last accessed June 24, 2020.

As of July 10, 2020, CDC has recorded approximately 99 outbreaks of COVID-19 onboard 123 ships within U.S. jurisdiction²² including 958 confirmed cases, 2,015 suspect/probable cases and 34 deaths. Of the 49 ships currently operating or planning to operate in U.S. waters during the period of the April 15, 2020 Extension, COVID-19 activity onboard continues and there still remain 10 “Provisionally Red” ships (i.e., reporting at least one confirmed case of COVID-19 or COVID-like illness in the past 28 days).

Since the issuance of the April 15, 2020 Extension, cruise ships with significant outbreaks involving passengers and crew, such as the *Celebrity Eclipse* (92 confirmed COVID-19 cases, 8 suspect/probable COVID-19-like illness cases) and the *Coral Princess* (29 confirmed, 107 suspect/probable, and 5 deaths), arrived on U.S. shores as other countries around the world closed their ports to cruise ships.²³ These outbreaks not only endangered those onboard and at seaports, but also exposed travelers and communities throughout the world as sick and exposed passengers from ships like the *Zandaam*²⁴ (10 confirmed, 233 suspect/probable, 7 deaths), *Ruby Princess*, and *Costa Luminosa* traversed international airports, boarded planes, and returned to their homes. The CDC does not have official case counts for the *Costa Luminosa* and *Ruby Princess*, which docked in foreign seaports; however, the media have reported that these two ships are responsible for a significant number of cases and deaths.¹⁴ These outbreaks have continued in crew members on ships like the *Disney Wonder*, on which a COVID-19 outbreak spanned 10 weeks and included 229 confirmed and 43 COVID-like illness cases among crew.

The current scientific evidence suggests that cruise ships pose a greater risk of COVID-19 transmission than other settings. A recent article published in the *Journal of Travel Medicine* by Rocklöv et al. demonstrated that the *Diamond Princess* cruise ship experienced an onboard R_0 (basic reproduction rate) for COVID-19 of 14.8 before ship-wide quarantine was enacted.²⁵ This means that each case onboard the *Diamond Princess* transmitted COVID-19 to approximately 15 other people. This reproduction rate is approximately four times higher than the R_0 of the original epicenter of the outbreak in Wuhan, China, which was 3.7, meaning that each person with COVID-19 in the early days of the outbreak in Wuhan transmitted the disease to approximately four other people. In late February/early March, 149 cases of PCR-confirmed COVID-19 (of 589 tour participants) were found among U.S. residents linked to Egyptian Nile Cruises. This heightened rate of transmission onboard cruise ships has been documented in other academic publications.^{9, 26} Cruise ship conditions amplified an already highly transmissible disease.

²² The U.S. Coast Guard considers certain ships operating outside of U.S. waters subject to their jurisdiction for emergency response purposes. These ships are not included in CDC’s calculations.

²³ The Pandemic at Sea. www.washingtonpost.com/graphics/2020/politics/cruise-ships-coronavirus/. Last accessed June 18, 2020.

²⁴ The Pariah Ship. www.bloomberg.com/features/2020-zaandam-pariah-ship/. Last accessed June 18, 2020.

²⁵ Rocklöv J, Sjödin H, Wilder-Smith A. COVID-19 Outbreak on the Diamond Princess Cruise Ship: Estimating the Epidemic Potential and Effectiveness of Public Health Countermeasures. *J. Travel Med.* 2020; 18;27(3):taaa030. doi: 10.1093/jtm/taaa030.

²⁶ Payne DC, Smith-Jeffcoat SE, Nowak G, et al. SARS-CoV-2 Infections and Serologic Responses from a Sample of U.S. Navy Service Members — USS Theodore Roosevelt, April 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:714–721. DOI: <http://dx.doi.org/10.15585/mmwr.mm6923e4>.

Rocklöv et al. surmised that this heightened rate of transmission is due to the high population density onboard on ships, which are typically more densely populated than cities or most other living situations. While this is one contributing factor, CDC's surveillance data acquired during the period of the NSO show that drastically decreasing population onboard does not extinguish transmission. Other factors likely contributing to onboard transmission are crew living and working in close quarters in a partially enclosed environment where social distancing may prove challenging even with a limited number of people onboard.

In addition, the recent investigation by Payne et al. of transmission onboard a U.S. Navy ship demonstrated high transmission rates and high rates of mild disease and asymptomatic infection among crew.²⁵ These mild presentations and asymptomatic cases make case detection and isolation and quarantine practices based on clinical presentation alone challenging. Thus, covert spread of infection among crew may keep the virus circulating from one voyage to the next. The Navy ship investigation also demonstrates the importance of avoiding onboard congregate settings. However, with limited dining options and work areas on board cruise ships, avoiding congregate settings is challenging for crew.

Numerous challenges have arisen in detecting COVID-19 transmission onboard ships. Although examples can be given from most cruise lines, the experiences of four Royal Caribbean ships, the *Vision of the Seas*, *Liberty of the Seas*, *Enchantment of the Seas*, and *Adventure of the Seas*, particularly illustrate how an undetected COVID-19 outbreak may occur. These four ships reported no confirmed COVID-19 cases or COVID-like illness in crew for 28 days or longer. However, when crew subsequently disembarked in countries that required shoreside testing, confirmed cases of COVID-19 were detected in 55 crew members. While CDC has recommended periodic random testing of symptomatic and asymptomatic crew, to our knowledge, only 20 of 49 ships currently operating or planning to operate in U.S. waters during the period of the April 15, 2020 Extension have performed testing.

While regular testing is not a panacea and a negative test result cannot be used to rule out infection conclusively,²⁷ the addition of viral testing can help detect infected crew members earlier and isolate them from others. Viral testing should be used along with other measures to decrease transmission,²⁸ such as symptom screening, isolation and quarantine, routine social distancing, and frequent handwashing. Unfortunately, testing requires a rapid turnaround of results to be useful, and this has proven particularly challenging for ships, even when in port. Difficulties may include lack of point-of-care testing onboard and inadequate staffing to collect, track and transport samples. When rapid testing is more available, regular, repeated testing of those on board, as recommended in other high-density workplace settings, may help to detect COVID-19 outbreaks. Absent wider availability and implementation of testing, undetected outbreaks of COVID-19 among crew are likely to reoccur.

²⁷ Watson J, Whiting PF, Brush JE. Interpreting a covid-19 test result. *BMJ* 2020; 369: m1808. doi: <https://doi.org/10.1136/bmj.m1808>

²⁸ Testing Strategy for Coronavirus (COVID-19) in High-Density Critical Infrastructure Workplaces after a COVID-19 Case Is Identified. www.cdc.gov/coronavirus/2019-ncov/community/worker-safety-support/hd-testing.html. Last accessed June 18, 2020

Lack of Consensus Among Cruise Ship Operators and Need for Additional Industry-led Efforts Regarding Safely Resuming Passenger Operations

Cruise ship operators have taken tentative steps to advance their public health response to COVID-19, improve safety, and achieve readiness to safely resume passenger operations. Under the co-chairmanship of former Health and Human Services Secretary Michael O. Leavitt, two cruise lines, RCL and NCLH, have assembled a team of subject-matter experts from a variety of disciplines under the moniker of the “Healthy to Sail Alliance.” The group intends “*over the next few months ... to conduct a robust, scientifically grounded exploration on issues of cruise line health and safety*” (emphasis added). Furthermore, this group states that it will “deliver to the cruise lines a set of public health recommendations that will provide participating cruise lines with a guide or pathway as they pursue their individual company efforts to achieve the confidence of regulators and passengers.”

Additionally, a variety of cruise lines have promoted interventions to manage COVID-19 onboard ships in both online and in print marketing materials. These interventions include enhanced stateroom cleaning, installation of new air filters, preboarding health screenings, increased social distancing, increased availability of hand sanitizer, and more self-service meal options. It would thus be of benefit to have further industry-led engagement as to which strategies, best practices, and procedures, either singularly or in combination, would be most effective in protecting the health of passengers, crew, and global communities.

CDC will continue to update its guidance and recommendations to specify basic safety standards and public health interventions based on the best scientific evidence available. CDC will also continue to consult with international maritime public health partners on ways to reduce COVID-19 transmission on ships and will continue to monitor the global COVID-19 situation.

Findings and Immediate Action

The difficulty to date of cruise ship operators to submit and adhere to appropriate NSO response plans during a time of limited operations, as well as ongoing concerns relating to non-compliance with disease prevention protocols and continued outbreaks of COVID-19 onboard cruise ships, highlight the need for further action prior to resuming passenger operations.

Accordingly, and consistent with 42 CFR §§ 70.2, 71.31(b), and 71.32(b), the Director of CDC (“Director”) finds that cruise ship travel exacerbates the global spread of COVID-19, that the scope of this pandemic is inherently and necessarily a problem that is international and interstate in nature, and such transmission has not been controlled sufficiently by the cruise ship industry or individual State or local health authorities. As described in the March 14, 2020 Order, cruise ship travel markedly increases the risk and impact of the COVID-19 disease epidemic within the United States. If unrestricted cruise ship passenger operations were permitted to resume, infected and exposed persons disembarking cruise ships would place federal partners (e.g., Customs and Border Protection and the U.S. Coast Guard), healthcare workers, port personnel, and communities at substantial unnecessary risk.

The Director also finds evidence to support a reasonable belief that cruise ships are or may be infected or contaminated with a quarantinable communicable disease.²⁹ This reasonable belief is based on information from epidemiologic and other data included in this document and the information described in the March 14, 2020 Order and the April 15, 2020 Extension. As a result, persons on board or seeking to board cruise ships may likely be or would likely become infected with or exposed to COVID-19 by virtue of being on board at a time when cases of COVID-19 are being reported in increasingly significant numbers globally.³⁰

Accordingly, under 42 CFR § 70.2, the Director determines that measures taken by State and local health authorities regarding COVID-19 onboard cruise ships are inadequate to prevent the further interstate spread of the disease.

This Order is not a rule within the meaning of the Administrative Procedure Act (“APA”), but rather an emergency action taken under the existing authority of 42 CFR §§ 70.2, 71.31(b), and 71.32(b). In the event that this Order qualifies as a rule under the APA, notice and comment and a delay in effective date are not required because there is good cause to dispense with prior public notice and the opportunity to comment on this Order.³¹ Considering the public health emergency caused by COVID-19 based, among other things, on its potential for spread on board cruise ships, it would be impracticable and contrary to the public health, and by extension the public interest, to delay the issuance and effective date of this Order. Similarly, if this Order qualifies as a rule per the definition in the APA, the Office of Information and Regulatory Affairs has determined that it would be a major rule, but there would not be a delay in its effective date as the agency has invoked the good cause provision of the APA.

If any provision in this Order, or the application of any provision to any carriers, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, persons, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

In accordance with 42 U.S.C. § 264(e), this Order shall supersede any provision under State law (including regulations and provisions established by political subdivisions of States), that conflict with an exercise of Federal authority, including instructions by U.S. Coast Guard or HHS/CDC personnel permitting ships to make port or disembark persons under stipulated conditions, under this Order.

This Order shall be enforceable through the provisions of 18 U.S.C. §§ 3559, 3571; 42 U.S.C. §§ 243, 268, 271; and 42 CFR §§ 70.18, 71.2.

²⁹ COVID-19 is a communicable disease for which quarantine is authorized under Section 361 of the Public Health Service Act (42 U.S.C. § 264) and 42 CFR §§ 70.1, 71.1, as listed in Executive Order 13295, as amended by Executive Orders 13375 and 13674.

³⁰ Since the March 14, 2020 Order, the number of global cases of COVID-19 reported by the World Health Organization (WHO) has risen from 142,534 to 12,102,328 as of July 10, 2020, with 551,046 deaths. *See* Situation Reports, WHO, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports>.

³¹ *See* 5 U.S.C. §§ 553(b)(B), (d)(3).

Therefore, in accordance with Sections 361 and 365 of the Public Health Service Act (42 U.S.C. §§ 264, 268) and 42 CFR §§ 70.2, 71.31(b), 71.32(b), for all cruise ships described above for the period described below, it is **ORDERED**:

Measures Related to Protecting Public Health of Communities Signed on March 14, 2020

These measures were implemented to provide public health authorities, in concert with the cruise ship industry, the necessary pause in operations to develop and implement an appropriate and robust plan (1) to prevent and mitigate the further spread of COVID-19 in communities, and (2) to prevent the spread of the disease onboard and ensure the health of cruise ship passenger and crew.

Accordingly, the following terms and conditions of the *No Sail Order and Other Measures Related to Operations* signed on March 14, 2020, as modified and extended by this ORDER, SHALL REMAIN IN EFFECT. Consequently, it remains ORDERED:

1. Cruise ship operators shall not disembark or reembark crew members except as directed by the USCG, in consultation with HHS/CDC personnel and, as appropriate, as coordinated with Federal, State, and local authorities.
2. Cruise ship operators shall not embark any new passengers or crew, except as approved by USCG, or other Federal authorities as appropriate, in consultation with HHS/CDC personnel.
3. While in port, the cruise ship operator shall observe health precautions as directed by HHS/CDC personnel.
4. The cruise ship operator shall comply with all HHS/CDC, USCG, and other Federal agency instructions to follow CDC recommendations and guidance for any public health actions relating to passengers, crew, ship, or any article or thing on board the ship, as needed, including by making ships' manifests and logs available and collecting any specimens for COVID-19 testing.

Measures Related to Protecting Public Health and Crew Safety Signed on April 9, 2020 and Made Effective on April 15, 2020

These measures were implemented to, among other things, ensure a safe environment for crew members to work and disembark by requiring the submission of appropriate NSO response plans by cruise ship operators as a condition of obtaining controlled free pratique³² to continue to engage in any cruise ship operations in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States.

³² Under 42 C.F.R. § 71.1, controlled free pratique means permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.

Accordingly, the terms and conditions of the *Modification and Extension of No Sail Order and Other Measures Related to Operations*, intended to protect public health and crew safety, signed on April 9, 2020, and made effective on April 15, 2020, as modified and extended by this ORDER, SHALL REMAIN IN EFFECT. Consequently, it remains ORDERED:

1. As a condition of obtaining controlled free pratique to continue to engage in any cruise ship operations in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, cruise ship operators shall develop, implement, and operationalize, an appropriate, actionable, and robust plan to prevent, mitigate, and respond to the spread of COVID-19 among crew onboard cruise ships.
2. As a condition of obtaining controlled free pratique to continue to engage in any cruise ship operations in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, the cruise ship operator shall make the plan described in paragraph 1, above, available to HHS/CDC and USCG personnel.
3. An appropriate plan is one that adequately prevents, mitigates, and responds to the spread of COVID-19 among crew onboard cruise ships and that, at a minimum, addresses the following elements:
 - a. Onboard surveillance of crew with acute respiratory illnesses, influenza-like illnesses, pneumonia, and COVID-19, including reporting to HHS/CDC on a weekly basis on overall case counts, methods of testing, and number of crew requiring hospitalization or medical evacuation;
 - b. Reports on the number of crew onboard the cruise ship and any increase in the numbers of crew with COVID-19 made to HHS/CDC and USCG on a daily basis for as long as the cruise ship is within waters subject to the jurisdiction of the United States.
 - c. Onboard monitoring of crew through temperature checks and medical screening, including addressing frequency of monitoring and screening;
 - d. Training of all crew on COVID-19 prevention, mitigation, and response activities;
 - e. Protocols for any COVID-19 testing, including details relating to the shore-side transport, administration, and operationalization of laboratory work if onboard laboratory work is not feasible;
 - f. Onboard isolation, quarantine, and social distancing protocols to minimize the risk of transmission and spread of COVID-19;
 - g. Onboard medical staffing, including number and type of staff, and equipment in sufficient quantity to provide a hospital level of care (e.g., ventilators, facemasks, personal protective equipment) for the infected so as to minimize the need for hospitalization onshore;
 - h. An outbreak management and response plan to provision and assist an affected cruise ship that relies on industry resources, e.g., mobilization of additional cruise ships or other vessels to act as “hospital” ship for the infected, “quarantine” ship for the exposed, and “residential” ship for those providing care and treatment, including the ability to transport individuals between ships as needed;
 - i. Categorization of affected crew into risk categories with clear stepwise approaches for care and management of each category;

- j. A medical care plan addressing onboard care versus evacuation to on-shore hospitals for critically ill crew, specifying how availability of beds for critically ill at local hospitals will be determined in advance and how the cruise ship operator will ensure acceptance at local medical facilities to treat the critically ill in a manner that limits the burden on Federal, State, and local resources and avoids, to the greatest extent possible, medivac situations. If medical evacuation is necessary arrangements for evacuation must be made with commercial resources (e.g., ship tender, chartered standby vessel, chartered airlift) and arrangements made with a designated medical facility that has agreed to accept such evacuees. All medical evacuation plans must be coordinated with the U.S. Coast Guard;
 - k. Detailed logistical planning for evacuating and repatriating both U.S. citizens and foreign nationals to their respective communities and home countries via foreign government or industry-chartered private transport and flights, including the steps the cruise ship operator will take to ensure those involved in the transport are not exposed (i.e., without the use of commercial flights to evacuate or repatriate individuals, whether within or from the United States);
 - l. The projected logistical and resource impact on State and local government and public health authorities and steps taken to minimize the impact and engage with these authorities; all plans must provide for industry/cruise line management of suspected or confirmed cases of COVID-19 without resource burden on Federal, State, or local governments;
 - m. Plan execution in all U.S. geographical areas – all plans must be capable of being executed anywhere in international, interstate, or intrastate waterways subject to the jurisdiction of the United States; and
 - n. Cleaning and disinfection protocols for affected cruise ships.
4. An appropriate plan shall be designed to minimize, to the greatest extent possible, any impact on U.S. government operations or the operations of any State or local government, or the U.S. healthcare system.
 5. The cruise ship operator shall further ensure that the plan is consistent with the most current CDC recommendations and guidance for any public health actions related to COVID-19. Where appropriate, a cruise ship operator may coordinate the development, implementation, and operationalization of a plan with other cruise ship operators, including an industry trade group.

Measures Related to Continued Protection of Public Health and Crew Safety

These measures are intended to continue to protect U.S. communities, ensure a safe environment for crew to work and disembark, and defer the embarkation of passengers until there is a clear pathway for a safe return to passenger operations.

Accordingly, it is **ORDERED**:

1. Cruise ship operators shall continue to suspend passenger operations and not embark passengers, except as approved by HHS/CDC personnel and USCG, in consultation with other federal authorities as appropriate.
2. As a condition of obtaining or retaining controlled free pratique to operate in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, cruise ship operators shall continue to follow CDC's *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew During the Period of the No Sail Order*, including reporting to HHS/CDC through weekly submission of the Enhanced Data Collection (EDC) form, as may be updated.³³ Additionally, cruise ship operators shall report to USCG via Advance Notice of Vessel Arrival (ANOA), whenever in U.S. waters.
3. As a condition of obtaining or retaining controlled free pratique to operate in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, cruise ship operators with appropriate NSO response plans shall continue to follow the *COVID-19 Color Coding System* requiring preventive measures for crew onboard based on the ship's status, as determined by HHS/CDC.
4. As a condition of obtaining or retaining controlled free pratique to operate in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, cruise ship operators with appropriate NSO response plans shall conduct viral testing for COVID-19 for crew in such a manner as described in the relevant CDC guidance with reporting of results on the EDC form.
5. As a condition of obtaining or retaining controlled free pratique to operate in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, cruise ship operators must observe the requirements of this Order, the previous Orders, and the most current CDC recommendations and guidance for any public health actions related to COVID-19, even when outside of U.S. waters for any ships that intend to return to U.S. waters during the period that this Order remains in effect.

This Order is effective upon signature and shall remain in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID-19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the order based on specific public health or other considerations; or (3) September 30, 2020.

³³ For cruise ship operators with ships that have not been in U.S. waters during the period of the No Sail Order or voluntarily withdrew their ships, the following conditions must be met prior to a ship returning to U.S. waters: 1) submission of the EDC form for 28-days preceding expected arrival in U.S. waters, and 2) a complete and accurate NSO response plan, including a signed Acknowledgment of No Sail Order Response Plan Completeness and Accuracy.

In testimony whereof, the Director, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, has hereunto set his hand at Atlanta, GA., this 16th day of July 2020.

A handwritten signature in black ink that reads "Robert R. Redfield MD". The signature is written in a cursive style with a horizontal line underneath the name.

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention,

EXHIBIT 5

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)**

**ORDER UNDER SECTIONS 361 & 365
OF THE PUBLIC HEALTH SERVICE ACT (42 U.S.C. 264, 268) AND
42 CODE OF FEDERAL REGULATIONS
PART 70 (INTERSTATE) AND PART 71 (FOREIGN):**

**THIRD MODIFICATION AND EXTENSION OF NO SAIL ORDER
AND OTHER MEASURES RELATED TO OPERATIONS**

Executive Summary

The coronavirus disease 2019 (COVID-19) pandemic continues to spread rapidly around the world with no approved treatment or vaccine. By July 16, 2020, the date of the second modification and extension of the No Sail Order, there were over 13 million confirmed cases and over 580,000 confirmed deaths worldwide. As of September 28, 2020, a cumulative total of over 33 million cases and almost 1 million confirmed deaths have now been reported worldwide. Even in countries that have managed to slow the rate of transmission, the risks for COVID-19 resurgence remains. In the United States, as of September 28, 2020, there have been over 7 million cases and more than 200,000 confirmed deaths with over 300,000 new cases reported in the last 7 days.

Since HHS/CDC's original No Sail Order, signed on March 14, 2020, which suspended the embarkation of passengers, CDC has worked to control the spread of the virus associated with COVID-19 on cruise ships that remained in U.S. jurisdiction, while protecting against further introduction and spread of the virus associated with COVID-19 into U.S. communities. Cruise ships continue to be an unsafe environment with close quarters where the disease spreads easily and is not readily detected.

Cumulative CDC data from March 1 through September 28, 2020, show a total of 3,689 confirmed cases of COVID-19¹ or COVID-like illness² cases on cruise ships and 41 deaths. These data have also revealed a total of 102 outbreaks on 124 different cruise ships, meaning more than 82% of ships within U.S. jurisdiction were affected by COVID-19 during this time frame. In addition, four cruise ships still have ongoing or resolving COVID-19 outbreaks on board. Recent outbreaks on cruise ships overseas continue to demonstrate that reduced capacity alone has not diminished transmission.

The challenges described in this document highlight the need for further action prior to cruise ships safely resuming passenger operations in the United States. CDC supports the decision by the Cruise Line International Association (CLIA) and its members to voluntarily extend the suspension of operations for passenger cruise ship travel through October 31, 2020.³ CDC further supports the decisions of numerous cruise ship operators that have voluntarily canceled

¹ Confirmed COVID-19 means laboratory confirmation for presence of SARS-CoV-2, the virus that causes COVID-19, by polymerase chain reaction (PCR) testing.

² COVID-like illness means acute respiratory illness (ARI), influenza-like illness (ILI), or diagnosis of pneumonia.

³ Press Release, *CLIA and Its Ocean-Going Cruise Line Members Announce Third Voluntary Suspension of U.S. Operations*, <https://cruising.org/en/news-and-research/press-room/2020/august/cli-a-announces-third-voluntary-suspension-of-us-cruise-operations> Last accessed September 30, 2020.

scheduled voyages involving U.S. ports beyond the date specified by CLIA, including Cunard,⁴ Crystal Cruises,⁵ Holland America,⁶ Oceania Cruises,⁷ Princess Cruise Lines,⁸ Viking Ocean Cruises,⁹ and Windstar Cruises.¹⁰

However, because not all cruise ship operators subject to the No Sail Order are members of CLIA or have made similar commitments, CDC is extending its No Sail Order to continue to protect the public's health by ensuring that passenger operations do not resume prematurely.

Previous Orders and Incorporation by Reference

This Order renews the No Sail Order and Other Measures Related to Operations signed by the CDC Director on March 14, 2020,¹¹ as further modified and extended effective April 15, 2020,¹²

⁴ Cunard Extends Pause in Operations, <https://www.cunard.com/en-us/contact-us/press-releases> Last accessed September 30, 2020.

⁵ <https://www.crystalcruises.com/advisory-alerts/voyage-cancellations>. Last accessed September 30, 2020.

⁶ Press Release, Holland America Line Extends Its Pause Of Cruise Operations To All Departures Through Dec. 15, 2020, https://www.hollandamerica.com/en_US/news/2020-press-releases/news-08112020-FurtherPauseAug11_Dec1520.html Last accessed September 30, 2020.

⁷ <https://www.oceaniacruises.com/coronavirus-statement>. Last accessed September 30, 2020.

⁸ Princess Cruises Extends Pause of Select Global Ship Operations Until December 15, https://www.princess.com/news/notices_and_advisories/notices/global-ship-operations-pause-december-2020.html. Last accessed September 30, 2020.

⁹ A letter from Chairman Torstein Hagen – August 12, 2020, <https://www.vikingcruises.com/oceans/my-trip/current-sailings/index.html> Last accessed September 30, 2020.

¹⁰ Windstar Cruises Travel Advisory – August 27, 2020, <https://www.windstarcruises.com/travel-health-advisory/> Last accessed September 30, 2020.

¹¹ No Sail Order and Suspension of Further Embarkation. <https://www.federalregister.gov/documents/2020/03/24/2020-06166/no-sail-order-and-suspension-of-further-embarkation>. Last accessed September 29, 2020.

¹² No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations. <https://www.federalregister.gov/documents/2020/04/15/2020-07930/no-sail-order-and-suspension-of-further-embarkation-notice-of-modification-and-extension-and-other>. Last accessed September 29, 2020.

and July 16, 2020¹³—subject to the modifications and additional stipulated conditions as set forth in this Order.

This Order shall remain in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID-19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the Order based on specific public health or other considerations; or (3) October 31, 2020.

The findings and other evidence relied upon in issuing the March 14 Order, and April 15 and July 16, 2020, modifications and extensions, are incorporated herein by reference. Any ambiguity or conflict between the March 14 Order, and April 15 and July 16 modifications and extensions, as further modified and extended by the current Order, shall be resolved in favor of the current Order.

Statement of Intent

This Order shall be interpreted and implemented in a manner as to achieve the following paramount objectives:

- Preserving human life;
- Preserving the health and safety of cruise ship crew members, port personnel, and communities;

¹³ No Sail Order and Suspension of Further Embarkation.
<https://www.federalregister.gov/documents/2020/07/21/2020-15810/no-sail-order-and-suspension-of-further-embarkation-second-modification-and-extension-of-no-sail>. Last accessed September 29, 2020.

- Preventing the further introduction, transmission, and spread of COVID-19 into and throughout the United States;
- Preserving the public health and other critical resources of Federal, State, and local governments;
- Preserving hospital, healthcare, and emergency response resources within the United States; and
- Maintaining the safety of shipping and harbor conditions.

Definitions

The following definitions shall apply for the purposes of this Order:

“COVID-19” means coronavirus disease 2019, the disease caused by the coronavirus SARS-CoV-2.

“Itinerary” means a plan to engage in operations.

“Layup” means reducing cruise ship operations to those levels needed to maintain essential machinery and equipment so that the ship may be returned to service at some future date.

“Operations,” “Operate,” and “Operating” in U.S. waters mean any action by a cruise ship operator (e.g., shifting berths, moving to anchor, discharging waste, making port, or embarking or disembarking passengers or crew) to bring or cause a cruise ship to be brought into or transit in or between any international, interstate, or intrastate waterways, that are subject to the

jurisdiction of the United States, or maintaining a ship in layup status in waters that are subject to the jurisdiction of the United States.

“Operator” means the Master of the vessel (cruise ship) and any other crew member responsible for cruise ship operations and navigation, as well as any person or entity (including a corporate entity) that authorizes or directs the use of a cruise ship (e.g., as owner, lessee, or otherwise). A cruise ship operator may be either the cruise ship captain or the cruise line to which the cruise ship belongs, or both. The term “Operator” as used in this Order further incorporates the terms “company,” “designated person,” and “responsible person” as defined in 33 CFR. § 96.120.

Applicability

This Modification and Extension of No Sail Order and Other Measures Related to Operations shall apply only to the subset of carriers¹⁴ described below and hereinafter referred to as “cruise ships”:

All commercial, non-cargo,¹⁵ passenger-carrying vessels with the capacity¹⁶ to carry 250¹⁷ or more individuals (passengers and crew) and with an itinerary anticipating an

¹⁴ Carrier is defined by 42 CFR § 71.1 to mean, “a ship, aircraft, train, road vehicle, or other means of transport, including military.”

¹⁵ Given the substantial risk of person-to-person transmission of COVID-19, as opposed to transmission via indirect contact, this Order is currently limited to passenger, non-cargo vessels.

¹⁶ A ship’s capacity shall be determined based on the number of persons listed in the U.S. Coast Guard Certificate of Inspection issued in accordance with 46 CFR § 2.01-5 and that was in effect on July 16, 2020.

¹⁷ Based on substantial epidemiologic evidence related to congregate settings and mass gatherings, this Order suspends operation of vessels with the capacity to carry 250 individuals or more. Evidence shows that settings as small as nursing homes or movie theaters can proliferate the spread of a communicable disease. As the numbers of passengers and crew on board a ship increase, certain recommended mitigation efforts such as social distancing become more difficult to implement. In light of the demonstrated rapid spread of COVID-19 in cruise ship settings,

overnight stay onboard or a twenty-four (24) hour stay onboard for either passengers or crew that are operating¹⁸ in international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States.¹⁹

This Order shall apply to cruise ships operating outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States during the period that this Order is in effect. The Order shall additionally apply regardless of whether the cruise ship operator has voluntarily agreed to suspend operations.

Background on CDC Actions to Control the Spread of COVID-19 on Cruise Ships

Under the No Sail Order, as modified and extended on April 15 and July 16, 2020, cruise ship operations were limited, and cruise ship operators required to submit plans to prevent, mitigate, and respond to the spread of COVID-19 as a condition of obtaining or retaining controlled free pratique to engage in cruise ship operations in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States. Cruise ship operators were also required to submit No Sail Order (NSO) response plans that ensured a safe environment for

application of this Order to vessels carrying 250 or more individuals is a prudent and warranted public health measure.

¹⁸ This Order does not apply to cruise ships that were in layup prior to March 14, 2020 and have continuously remained in lay-up status since that date.

¹⁹ This Order shall not apply to vessels operated by a U.S. Federal or State government agency. Nor shall it apply to vessels being operated solely for purposes of the provision of essential services, such as the provision of medical care, emergency response, activities related to public health and welfare, or government services, such as food, water, and electricity.

crew to work and disembark, and that minimized the impact on U.S. government operations or the operations of any state or local government, or the U.S. healthcare system.

As of April 29, 2020, seven²⁰ cruise ship operators submitted NSO response plans representing 108 cruise ships or about 95% of cruise ships subject to the April 15, 2020, modification and extension. As of September 6, all five²¹ cruise ship operators with ships remaining in U.S. waters have NSO response plans that are complete, accurate, and acknowledged. Only 31 out of the 108 ships (29%) that were in U.S. waters at the start of the NSO modification and extension on April 15 remain in U.S. waters as of September 28, 2020. Pending approval of a cruise ship operator's NSO response plan, CDC allowed cruise ship operators to disembark and repatriate crew members from cruise ships in U.S. waters if the operator attested to complying with requirements to disembark crew members through noncommercial means so as to minimize the risk to other travelers and communities. Through this non-commercial travel attestation process, CDC worked with cruise ship operators to assist in the disembarkation and safe return home of approximately 8,990 crew members, including 329 U.S. citizens and residents.

CDC published its *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew During the Period of the No Sail Order* to assist cruise ship operators in preventing, detecting, and medically managing confirmed and suspected cases of COVID-19 and exposures among

²⁰ These operators included Bahamas Paradise Cruise Lines, Carnival Corporation, Disney Cruise Lines, Norwegian Cruise Line Holdings, Royal Caribbean Group, Virgin Voyages, and Windstar Cruises. MSC Cruises submitted an NSO response plan on May 7, 2020, covering three of its ships.

²¹ Carnival Corporation, Virgin Voyages, and Windstar Cruises initially submitted NSO response plans but later withdrew their ships from U.S. waters. Accordingly, CDC has held its review of these NSO response plans in abeyance.

crew members.²² CDC also established an enhanced surveillance process to provide a more complete picture of COVID-19 activity on cruise ships. Under the *Interim Guidance*, CDC requires weekly submission of the “Enhanced Data Collection (EDC) During COVID-19 Pandemic Form.”²³

COVID-19 often presents as mild illness and many cases are asymptomatic among people of all ages. When symptoms are present, they are nonspecific and similar to those of many other respiratory infections and noninfectious conditions such as seasonal allergies. CDC *Interim Guidance* recommended that cruise ships’ surveillance include routine viral testing for COVID-19, including intermittent testing of a random sample of symptomatic and asymptomatic crew members. Viral tests diagnose acute infection; the U.S. Food and Drug Administration-authorized viral tests include those that detect SARS-CoV-2 nucleic acid (i.e., polymerase chain reaction [PCR]) or antigen (a rapid test).

However, availability of such routine viral testing on cruise ships remains limited. For these reasons, CDC does not limit its data collection to just confirmed cases of COVID-19 but collects data on both confirmed cases and COVID-like illness. These data create a more accurate picture of the spread of COVID-19 and its effects in the United States and provide additional data to inform the national public health response. As of September 28, EDC reports have shown a total of 6,088 PCR tests performed, 294 (5%) of which were positive for COVID-19; 24

²² CDC, *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew During the Period of the No Sail Order* at: <https://www.cdc.gov/quarantine/cruise/management/interim-guidance-no-sail-order.html>

²³ This EDC Form is used to conduct surveillance for COVID-19 among crew who remain on board cruise ships using cumulative reports of acute respiratory illness (ARI), influenza-like illness (ILI), and pneumonia, and other clinical indicators.

hospitalizations; two instances of mechanical ventilation; and 15 medical evacuations for crew on ships within U.S. jurisdiction since April 13, 2020.

CDC established a “COVID-19 Color Coding System” for ships applicable to cruise ship operators with an appropriate NSO response plan for crew management. Classification of ships under this system requires cruise company officials to sign an acknowledgment of the completeness and accuracy of their NSO response plans upon completion of CDC review of the plan. CDC additionally provides a provisional color status for ships belonging to cruise ship operators that do not yet have a complete and accurate plan. CDC assesses the status of a ship by reviewing surveillance data from the weekly EDC form as well as recent embarkations or crew transfers. Additional details regarding the color-coding system and color coding status for individual ships (which is updated weekly) may be found at <https://www.cdc.gov/coronavirus/2019-ncov/travelers/crew-disembarkations-commercial-travel.html>.

Since July 16, 2020, CDC has conducted implementation checks on 11 cruise ships operating in U.S. jurisdiction to review compliance with the NSO. These implementation checks showed that cruise ship operators were adhering to the requirements of the NSO and their NSO response plans.

Challenges and Limitations in Testing Crew on Cruise Ships During the NSO

While cruise ship operators have adhered to their NSO response plans during this time of suspended passenger operations, challenges remain. These challenges include the limitations of

viral test results, including the possibility of false negative test results, the importance of crew quarantine in preventing disease spread, and concerns relating to reporting of symptoms by crew.

Two specific cases help illustrate these challenges. In the first case, following a cruise ship operator's policy to test all newly embarking crew prior joining a ship, a crew member was tested in his home country and found to be PCR-negative for COVID-19 prior to flying to the United States to board the ship. Pursuant to CDC recommendations, the crew member immediately began a 14-day quarantine in a private cabin, and other crew members sanitized his boarding pathway after embarkation. Approximately 9 hours later during a routine temperature check, the crew member was found dead in bed.²⁴ The cruise line contacted the decedent's family who reported that the crew member had a dry cough and itchy throat prior to traveling despite reporting no symptoms during the pre-boarding process. A postmortem nasopharyngeal swab was collected for PCR testing, and the result was positive for COVID-19.

In the second case, another crew member onboard the same ship was tested in his home country and was also PCR-negative for COVID-19 prior to flying to the United States to board the ship. Again, pursuant to CDC recommendations, the crew member immediately began a 14-day quarantine in a private cabin, and other crew members sanitized his boarding pathway after embarkation. During this quarantine period, the crew member developed symptoms of nasal congestion and upon examination was found to have a rapid heart rate without a fever. When the cruise ship performed PCR testing of all 174 crew, this crew member was the only one who

²⁴ This case is included in CDC's count of deaths from COVID-19 based on the positive PCR test result and lack of any other apparent explanation for the cause of death.

tested positive for COVID-19, indicating that the crew member became infected in the crew member's home country before travel.

These cases illustrate the importance of the 14-day quarantine period for embarking crew and how test results cannot eliminate the need for or reduce the length of quarantine. Testing represents a snapshot in time. A negative test result means that the virus that causes COVID-19 was not found in the sample collected. However, it is possible for any test to give a negative result that is incorrect ("false negative") in some people with COVID-19; testing may also be negative while a person is in the 2–14-day incubation period for COVID-19. The accuracy of any diagnostic test depends on many factors, including whether the sample was collected properly, whether the sample was maintained in appropriate conditions while it was shipped to the laboratory, and when during the course of the infection the testing was conducted.

When viral testing is negative, the possibility of a false negative result should be considered in the context of the individual's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should be considered especially if recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing should be considered by healthcare providers in consultation with public health authorities.

As these cases illustrate, a single negative test result cannot be used to rule out the possibility of COVID-19, especially if the individual may have been recently exposed to the virus or is displaying symptoms. Relying on crew testing alone without quarantine would not have been

enough to prevent these two infected crew members from exposing others onboard. Despite preboarding screening efforts, one of these crew members was also reluctant to report symptoms. These factors should be considered carefully by cruise ship operators in planning for an eventual return to passenger operations.

Dangers of Prematurely Resuming Passenger Operations on Cruise Ships

There have been several recent instances of outbreaks of COVID-19 onboard cruise ships in those countries that have allowed passenger operations to resume, despite cruise ship operators implementing measures to control the disease. On the Hurtigruten cruise ship *MS Roald Amundsen*, 41 crew members and 21 passengers were confirmed to have COVID-19 after two voyages occurring between July 17–24 and July 25–31 in Norway.²⁵ The ship had 209 passengers on the first voyage and 178 on the second.²⁶ The cruise ship operator permitted passengers to disembark on July 31, before the announcement of the outbreak, potentially spreading the virus to dozens of towns and villages along Norway’s western coast and setting off an effort by public health authorities to trace and locate the nearly 400 potentially exposed passengers.²⁷ While the outbreak onboard the *MS Roald Amundsen* is still under investigation, Hurtigruten has revealed that its internal review “uncovered several deviations from procedures,

²⁵ *Hurtigruten crew members and guests test positive for COVID-19*, <https://www.hurtigruten.com/practical-information/coronavirus-update/ra31072020/>. Last accessed September 30, 2020.

²⁶ AP News, *Outbreak hits Norway cruise ship, could spread along coast*, <https://apnews.com/781a3fa3faabde06d44749bfe57139da>. Last accessed September 30, 2020.

²⁷ Maritime Executive, *Hurtigruten's COVID-19 Fallout Continues*, <https://www.maritime-executive.com/index.php/article/fallout-continues-from-hurtigruten-s-covid-19-incident>. Last accessed September 30, 2020.

for example when it comes to quarantining foreign crews and the internal flow of important information.”²⁸

Cases of COVID-19 have also been documented on other cruise ships that have attempted to resume passenger operations. The SeaDream Yacht Club temporarily halted cruising onboard the *SeaDream I* in July after a passenger who had previously shown no symptoms disembarked from the ship and tested positive for COVID-19 upon returning to his home country of Denmark.²⁹ The Tahiti-based Paul Gauguin cruises had a passenger test positive for COVID-19 just three days into its first voyage with international passengers.³⁰ The incident required the French Polynesia High Commission to initiate a contact-tracing investigation to determine who may have been exposed to the passenger in question.³¹ About 148 passengers and 192 crew members were on board the cruise ship at the time.³² In late July, ten crew members on board AIDA Cruises’ *AIDAblu* and *AIDamar* tested positive for COVID-19 after boarding in Rostok, Germany.³³ In the United States, Uncruise Adventures canceled its remaining voyages in Alaska after a passenger on board the 60-person³⁴ passenger vessel *Wilderness Adventurer* tested positive for COVID-19.³⁵ The incident necessitated a contact tracing investigation by Alaska

²⁸ *The COVID-19 situation: Update from Hurtigruten*, <https://presse.hurtigruten.no/pressreleases/the-covid-19-situation-update-from-hurtigruten-3024635>. Last accessed September 30, 2020.

²⁹ Travel Weekly, *Another small-ship line reports a passenger with a positive Covid test*, <https://www.travelweekly.com/Cruise-Travel/SeaDream-reports-passenger-with-a-positive-Covid-test>. Last accessed September 30, 2020.

³⁰ The Maritime Executive, *One Suspected COVID-19 Case On Cruise Ship Paul Gauguin*, <https://www.maritime-executive.com/article/one-suspected-covid-19-case-on-cruise-ship-paul-gauguin>. Last accessed September 30, 2020.

³¹ *Id.*

³² *Id.*

³³ USA Today, *Ten AIDA cruise crew members test positive for COVID-19; ships will still sail in August*, <https://www.usatoday.com/story/travel/cruises/2020/07/28/aida-cruises-crew-members-test-positive-covid-19/5525310002/>. Last accessed September 30, 2020.

³⁴ This is below the capacity established by the NSO for passenger-carrying vessels.

³⁵ Uncruise Adventures, Press Release, <https://www.uncruise.com/about-us/media/press-releases/covid-cruise-not-uncruise-adventures>. Last accessed September 30, 2020.

public health authorities and the quarantine of passengers at a hotel in Juneau and of crew on board the ship.³⁶

In the above examples, cruise ship operators had health and safety protocols to prevent the transmission and spread of COVID-19. The protocols adopted by the Hurtigruten included new sanitation measures, elimination of self-serve buffet dining, implementation of onboard social distancing procedures, operating at 50% capacity, a preboarding health questionnaire, and restricted shore excursions.³⁷ While investigations are still ongoing, the statement by Hurtigruten's CEO that the company failed to abide by its own protocols³⁸ suggests a need for further education, training, and experience in implementing new health and safety protocols prior to resuming passenger operations in any significant capacity.

In these examples, even when health and safety protocols were apparently observed, resuming passenger operations significantly burdened public health authorities by creating the need for additional testing, contact tracing, and quarantine. While the SeaDream Yacht Club has claimed that the passenger on board the *SeaDream I* was a "false positive," a statistically rare event,³⁹ the incident still necessitated the quarantine of passengers and non-essential crew as directed by the

³⁶ *Id.*

³⁷ <https://www.hurtigruten.com/practical-information/health-and-safety-on-board/>. Last accessed September 30, 2020.

³⁸ Seatrade Cruise News, 'Mistakes were made ... We failed' to follow own coronavirus protocols: Hurtigruten CEO, <https://www.seatrade-cruise.com/news/mistakes-were-made-we-failed-follow-own-coronavirus-protocols-hurtigruten-ceo>. Last accessed September 30, 2020.³⁹ Watson J, Whiting PF, Brush JE. Interpreting a covid-19 test result. *BMJ* 2020; 369: m1808. doi: <https://www.bmj.com/content/369/bmj.m1808>. Last accessed September 30, 2020.

³⁹ Watson J, Whiting PF, Brush JE. Interpreting a covid-19 test result. *BMJ* 2020; 369: m1808. doi: <https://www.bmj.com/content/369/bmj.m1808>. Last accessed September 30, 2020.

Norwegian Directorate of Health as a public health precaution.⁴⁰ Paul Gauguin cruises required passengers to present proof of a negative COVID-19 test (PCR) at embarkation, excluding residents and visitors who had been in French Polynesia for more than 14 days,⁴¹ yet the French Polynesia High Commission still conducted a lengthy contact investigation after a passenger later tested positive. The ship was carrying approximately 148 passengers (less than half of its 332-guest capacity) and 192 crew members at the time of the outbreak.⁴² In the case of the AIDA cruise ships, all ten crew members initially tested negative in their home countries of Indonesia and the Philippines, yet when retested upon arrival in Germany were determined to be positive and required isolation on board the cruise ships.⁴³ A quarantine under the supervision of the local public health authority was similarly required when a passenger who had tested negative upon boarding the Uncruise Adventures' *Wilderness Adventurer* subsequently tested positive. In these examples, voyages were cancelled, passengers and crew quarantined or isolated, and contact tracing investigations conducted for those on the ship and for passengers who had returned to their home communities.

More Time Needed to Assess Effectiveness of Proposed Public Health Interventions Prior to Resuming Passenger Operations

⁴⁰ The Maritime Executive, *Third Cruise Ship in a Week Reports COVID-19 Situation in Norway*, <https://www.maritime-executive.com/article/third-cruise-ship-in-a-week-reports-covid-19-situation-in-norway>. Last accessed September 30, 2020.

⁴¹ <https://www.pgcruises.com/travel-advisory>. Last accessed September 30, 2020.

⁴² *Paul Gauguin Ship Returns to Port After Suspected COVID-19 Case*, <https://www.msn.com/en-us/travel/news/paul-gauguin-ship-returns-to-port-after-suspected-covid-19-case/ar-BB17wniX>. Last accessed September 30, 2020.

⁴³ Crew Center, *10 Crew Members of AIDA Cruises Test Positive for COVID-19*, <https://crew-center.com/10-crew-members-aida-cruises-test-positive-covid-19>. Last accessed September 30, 2020.

Cruise ship operators have taken steps to advance their public health response to COVID-19, improve safety, and achieve readiness to safely resume passenger operations. Under the co-chairmanship of former Health and Human Services Secretary Michael O. Leavitt, two cruise lines, Royal Caribbean Group and Norwegian Cruise Line Holdings, assembled a “Healthy Sail Panel” of subject-matter experts from a variety of disciplines.⁴⁴ The World Travel & Tourism Council (WTTC) and Carnival Corporation also recently hosted a global science summit on COVID-19 designed, “to inform practical, adaptable and science-based solutions for mitigating and living with COVID-19.”⁴⁵ MSC Cruises further established its own industry-led panel with “competency to review policy initiatives, technical innovations, or operational measures related to COVID-19,”⁴⁶ and will presumably implement these recommendations as its passenger operations continue to resume in the Mediterranean with residents of Schengen countries.⁴⁷ At the moment, however, it is too early to assess whether these initiatives will produce a viable set of policies and practices that will mitigate the transmission and spread of COVID-19 onboard cruise ships while minimizing the potential burden and need for public health response activities.

To gather more information regarding these industry-led efforts and solicit public input, on July 20, 2020, CDC published a Request for Information (RFI) in the Federal Register related to cruise ship planning and infrastructure, resumption of passenger operations, and additional

⁴⁴ <https://www.rclcorporate.com/royal-caribbean-group-and-norwegian-cruise-line-holdings-form-healthy-sail-panel/>. Last accessed September 30, 2020.

⁴⁵ Press Release, <https://www.carnivalcorp.com/news-releases/news-release-details/world-leading-experts-headline-covid-19-summit-hosted-wttc>. Last accessed September 30, 2020.

⁴⁶ MSC Cruise Announces Blue-Ribbon COVID Expert Group, Engages Specialized Maritime Classification Society to Provide Third-Party Verification That Its Protocol Meets Established Guidance, <https://www.msccruisesusa.com/news/blue-ribbon-covid-expert-group>. Last accessed September 30, 2020.

⁴⁷ Cruise Critic News, MSC Cruises Restarts Cruising in the Mediterranean, <https://www.cruise critic.com/news/5533/>. Last accessed September 30, 2020.

summary questions.⁴⁸ The document had a comment period that ended on September 21, 2020 and almost 13,000 comments were received. In light of the number of submissions and high level of public interest, additional time is needed for CDC to review these comments, which may be used to inform future public health guidance and preventive measures relating to travel on cruise ships.

Findings and Immediate Action

The continued spread of the COVID-19 pandemic worldwide, risk of resurgence in countries that have suppressed transmission, ongoing concerns related to the restart of cruising internationally, and need for additional time to assess industry measures to control potential COVID-19 onboard cruise ships with passengers without burdening public health, support continuing to defer resumption of passenger operations at this time.

Accordingly, and consistent with 42 CFR §§ 70.2, 71.31(b), and 71.32(b), the Director of CDC (“Director”) continues to find that cruise ship travel exacerbates the global spread of COVID-19, that the scope of this pandemic is inherently and necessarily a problem that is international and interstate in nature, and such transmission has not been controlled sufficiently by the cruise ship industry or individual State or local health authorities. As described in the March 14, 2020, Order, cruise ship travel markedly increases the risk and impact of the COVID-19 disease epidemic within the United States. If unrestricted cruise ship passenger operations were

⁴⁸ Request for Information Related to Cruise Ship Planning and Infrastructure, Resumption of Passenger Operations, and Summary Questions, <https://www.federalregister.gov/documents/2020/07/21/2020-15812/request-for-information-related-to-cruise-ship-planning-and-infrastructure-resumption-of-passenger>. Last accessed September 30, 2020.

permitted to resume, infected and exposed persons disembarking cruise ships would place federal partners (e.g., Customs and Border Protection and the U.S. Coast Guard), healthcare workers, port personnel, and communities at substantial unnecessary risk.

The Director also continues to find evidence to support a reasonable belief that cruise ships are or may be infected or contaminated with a quarantinable communicable disease.⁴⁹ This reasonable belief is based on information from epidemiologic and other data included in this document and the information described in the March 14, 2020, Order and the April 15 and July 16, 2020, modifications and extensions. As a result, persons on board or seeking to board cruise ships may likely be or would likely become infected with or exposed to COVID-19 by virtue of being on board at a time when cases of COVID-19 continue to be reported in increasingly significant numbers globally.⁵⁰ Additionally, persons infected on cruise ships would be likely to transmit COVID-19 to U.S. communities by traveling interstate after cruising.

Accordingly, under 42 CFR § 70.2, the Director determines that measures taken by State and local health authorities regarding COVID-19 onboard cruise ships are inadequate to prevent the further interstate spread of the disease.

This Order is not a rule within the meaning of the Administrative Procedure Act (“APA”), but rather an emergency action taken under the existing authority of 42 CFR §§ 70.2, 71.31(b), and

⁴⁹ COVID-19 is a communicable disease for which quarantine is authorized under Section 361 of the Public Health Service Act (42 U.S.C. § 264) and 42 CFR §§ 70.1, 71.1, as listed in Executive Order 13295, as amended by Executive Orders 13375 and 13674.

⁵⁰ Since the March 14, 2020, Order, the number of global cases of COVID-19 reported by the World Health Organization (WHO) has risen from 142,534 to more than 33 million as of September 28, 2020, with more than 1 million deaths. *See* Situation Reports, WHO, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports>.

71.32(b). In the event that this Order qualifies as a rule under the APA, notice and comment and a delay in effective date are not required because there is good cause to dispense with prior public notice and the opportunity to comment on this Order.⁵¹ Considering the public health emergency caused by COVID-19 based on, among other things, its potential for spread on board cruise ships, it would be impracticable and contrary to the public's health, and by extension the public's interest, to delay the issuance and effective date of this Order. Similarly, if this Order qualifies as a rule per the definition in the APA, the Office of Information and Regulatory Affairs has determined that it would be a major rule, but there would not be a delay in its effective date as the agency has invoked the good cause provision of the APA.

If any provision in this Order, or the application of any provision to any carriers, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, persons, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

In accordance with 42 U.S.C. § 264(e), this Order shall supersede any provision under State law (including regulations and provisions established by political subdivisions of States), that conflict with an exercise of Federal authority, including instructions by U.S. Coast Guard or HHS/CDC personnel permitting ships to make port or disembark persons under stipulated conditions, under this Order.

⁵¹ See 5 U.S.C. §§ 553(b)(B), (d)(3).

This Order shall be enforceable through the provisions of 18 U.S.C. §§ 3559, 3571; 42 U.S.C. §§ 243, 268, 271; and 42 CFR §§ 70.18, 71.2.

Therefore, in accordance with Sections 361 and 365 of the Public Health Service Act (42 U.S.C. §§ 264, 268) and 42 CFR §§ 70.2, 71.31(b), 71.32(b), for all cruise ships described above for the period described below, it is **ORDERED**:

Measures Related to Protecting Public Health of Communities Signed on March 14, 2020

These measures were implemented to provide public health authorities, in concert with the cruise ship industry, the necessary pause in operations to develop and implement an appropriate and robust plan (1) to prevent and mitigate the further spread of COVID-19 in communities, and (2) to prevent the spread of the disease onboard and ensure the health of cruise ship passenger and crew.

Accordingly, the following terms and conditions of the *No Sail Order and Other Measures Related to Operations* signed on March 14, 2020, as modified and extended by this ORDER, SHALL REMAIN IN EFFECT. Consequently, it remains ORDERED:

1. Cruise ship operators shall not disembark or reembark crew members except as directed by the USCG, in consultation with HHS/CDC personnel and, as appropriate, as coordinated with Federal, State, and local authorities.

2. Cruise ship operators shall not embark any new passengers or crew, except as approved by USCG, or other Federal authorities as appropriate, in consultation with HHS/CDC personnel.
3. While in port, the cruise ship operator shall observe health precautions as directed by HHS/CDC personnel.
4. The cruise ship operator shall comply with all HHS/CDC, USCG, and other Federal agency instructions to follow CDC recommendations and guidance for any public health actions relating to passengers, crew, ship, or any article or thing on board the ship, as needed, including by making ships' manifests and logs available and collecting any specimens for COVID-19 testing.

Measures Related to Protecting Public Health and Crew Safety Signed on April 9, 2020, and Made Effective on April 15, 2020

These measures were implemented to, among other things, ensure a safe environment for crew members to work and disembark by requiring the submission of appropriate NSO response plans by cruise ship operators as a condition of obtaining controlled free pratique⁵² to continue to engage in any cruise ship operations in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States.

⁵² Under 42 C.F.R. § 71.1, controlled free pratique means permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.

Accordingly, the terms and conditions of the *Modification and Extension of No Sail Order and Other Measures Related to Operations*, intended to protect public health and crew safety, signed on April 9, 2020, and made effective on April 15, 2020, as modified and extended by this ORDER, SHALL REMAIN IN EFFECT. Consequently, it remains ORDERED:

1. As a condition of obtaining controlled free pratique to continue to engage in any cruise ship operations in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States, cruise ship operators shall develop, implement, and operationalize, an appropriate, actionable, and robust plan to prevent, mitigate, and respond to the spread of COVID-19 among crew onboard cruise ships.
2. As a condition of obtaining controlled free pratique to continue to engage in any cruise ship operations in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States, the cruise ship operator shall make the plan described in paragraph 1, above, available to HHS/CDC and USCG personnel.
3. An appropriate plan is one that adequately prevents, mitigates, and responds to the spread of COVID-19 among crew onboard cruise ships and that, at a minimum, addresses the following elements:
 - a. Onboard surveillance of crew with acute respiratory illnesses, influenza-like illnesses, pneumonia, and COVID-19, including reporting to HHS/CDC on a weekly basis on overall case counts, methods of testing, and number of crew requiring hospitalization or medical evacuation;

- b. Reports on the number of crew onboard the cruise ship and any increase in the numbers of crew with COVID-19 made to HHS/CDC and USCG on a daily basis for as long as the cruise ship is within waters subject to the jurisdiction of the United States.
- c. Onboard monitoring of crew through temperature checks and medical screening, including addressing frequency of monitoring and screening;
- d. Training of all crew on COVID-19 prevention, mitigation, and response activities;
- e. Protocols for any COVID-19 testing, including details relating to the shore-side transport, administration, and operationalization of laboratory work if onboard laboratory work is not feasible;
- f. Onboard isolation, quarantine, and social distancing protocols to minimize the risk of transmission and spread of COVID-19;
- g. Onboard medical staffing, including number and type of staff, and equipment in sufficient quantity to provide a hospital level of care (e.g., ventilators, facemasks, personal protective equipment) for the infected so as to minimize the need for hospitalization onshore;
- h. An outbreak management and response plan to provision and assist an affected cruise ship that relies on industry resources, e.g., mobilization of additional cruise ships or other vessels to act as “hospital” ship for the infected, “quarantine” ship for the exposed, and “residential” ship for those providing care and treatment, including the ability to transport individuals between ships as needed;
- i. Categorization of affected crew into risk categories with clear stepwise approaches for care and management of each category;

- j. A medical care plan addressing onboard care versus evacuation to on-shore hospitals for critically ill crew, specifying how availability of beds for critically ill at local hospitals will be determined in advance and how the cruise ship operator will ensure acceptance at local medical facilities to treat the critically ill in a manner that limits the burden on Federal, State, and local resources and avoids, to the greatest extent possible, medivac situations. If medical evacuation is necessary arrangements for evacuation must be made with commercial resources (e.g., ship tender, chartered standby vessel, chartered airlift) and arrangements made with a designated medical facility that has agreed to accept such evacuees. All medical evacuation plans must be coordinated with the U.S. Coast Guard;
- k. Detailed logistical planning for evacuating and repatriating both U.S. citizens and foreign nationals to their respective communities and home countries via foreign government or industry-chartered private transport and flights, including the steps the cruise ship operator will take to ensure those involved in the transport are not exposed (i.e., without the use of commercial flights to evacuate or repatriate individuals, whether within or from the United States);
- l. The projected logistical and resource impact on State and local government and public health authorities and steps taken to minimize the impact and engage with these authorities; all plans must provide for industry/cruise line management of suspected or confirmed cases of COVID-19 without resource burden on Federal, State, or local governments;
- m. Plan execution in all U.S. geographical areas – all plans must be capable of being executed anywhere in international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States; and

- n. Cleaning and disinfection protocols for affected cruise ships.
4. An appropriate plan shall be designed to minimize, to the greatest extent possible, any impact on U.S. government operations or the operations of any State or local government, or the U.S. healthcare system.
5. The cruise ship operator shall further ensure that the plan is consistent with the most current CDC recommendations and guidance for any public health actions related to COVID-19. Where appropriate, a cruise ship operator may coordinate the development, implementation, and operationalization of a plan with other cruise ship operators, including an industry trade group.

Measures Related to Continued Protection of Public Health and Crew Safety Signed on July 16, 2020, as Modified and Extended by this ORDER

These measures were intended to continue to protect U.S. communities, ensure a safe environment for crew to work and disembark, and defer the embarkation of passengers until there is a clear pathway for a safe return to passenger operations.

Accordingly, the terms and conditions of the *Second Modification and Extension of No Sail Order and Other Measures Related to Operations*, signed on July 16, 2020, as modified and extended by this ORDER, SHALL REMAIN IN EFFECT.

Consequently, it remains **ORDERED**:

1. Cruise ship operators shall continue to suspend passenger operations and not embark passengers, except as approved by HHS/CDC personnel and USCG, in consultation with other federal authorities as appropriate.
2. As a condition of obtaining or retaining controlled free pratique to operate in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States, cruise ship operators shall continue to follow CDC's *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew During the Period of the No Sail Order*, including reporting to HHS/CDC through weekly submission of the Enhanced Data Collection (EDC) form, as may be updated. Additionally, cruise ship operators shall report to USCG via Advance Notice of Vessel Arrival (ANOA), whenever in U.S. waters.
3. For cruise ship operators with ships that have not been in U.S. waters during the period of the No Sail Order or voluntarily withdrew their ships, the following conditions must be met prior to a ship returning to U.S. waters: 1) submission of the EDC form for 28-days preceding expected arrival in U.S. waters; and 2) having a complete and accurate NSO response plan, including having submitted to CDC a signed *Acknowledgment of No Sail Order Response Plan Completeness and Accuracy*.
4. As a condition of obtaining or retaining controlled free pratique to operate in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States, cruise ship operators with appropriate NSO response plans shall continue

to follow the *COVID-19 Color Coding System for Cruise Ships During the Period of the No Sail Order* requiring preventive measures for crew onboard based on the ship's status, as determined by HHS/CDC.

5. As a condition of obtaining or retaining controlled free pratique to operate in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States, cruise ship operators with appropriate NSO response plans shall conduct viral testing for COVID-19 for crew in such a manner as described in the relevant CDC guidance with reporting of results on the EDC form.

6. As a condition of obtaining or retaining controlled free pratique to operate in any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States, cruise ship operators must observe the requirements of this Order, the previous Orders, and the most current CDC recommendations and guidance for any public health actions related to COVID-19, even when outside of U.S. waters for any ships that intend to return to U.S. waters during the period that this Order remains in effect.

This Order is effective upon signature and shall remain in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID-19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the order based on specific public health or other considerations; or (3) October 31, 2020.

In testimony whereof, the Director, Centers for Disease Control and Prevention, U.S.
Department of Health and Human Services, has hereunto set his hand at Washington, D.C., this
30th day of September 2020.

A handwritten signature in black ink that reads "Robert R. Redfield MD". The signature is written in a cursive style with a large initial 'R'.

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention

EXHIBIT 6

RE Senate HELP Committee Hearing

March 18, 2021

PHIPPS REPORTING

Raising the Bar!

March 18, 2021

RE:

Senate HELP Committee Hearing Excerpt: Examining
Our COVID-19 Response: An Update from Federal
Officials

_____ /

TRANSCRIPT OF VIDEO RECORDING

Senate HELP Committee Hearing Excerpt

March 18, 2021

STENOGRAPHICALLY TRANSCRIBED AUDIO RECORDING BY:
Amory Ranck, Florida Professional Reporter

Job Number 181918

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1 Thereupon, the following proceeding was transcribed
2 from an audio recording:

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4 SENATOR MURKOWSKI: It's not very often
5 that Alaska makes the news in the good news
6 category when it comes to health and our
7 statistics but we're number one.

8 We have moved out earlier in terms of the
9 vaccination of Alaskans. Right now it's
10 18.9 percent that are fully vaccinated,
11 28 percent have received their first vaccine.
12 We have some communities that are approaching
13 90 percent vaccination. So we're pretty proud
14 of that. The rest of the country is looking at
15 the model as to how we were able to do it, open
16 it up to everybody over 16.

17 I think you're looking at that. You don't
18 perhaps need to follow the model of us
19 delivering the vaccine to the clinics by way of
20 snow machine with a sled in back, but the model
21 is good and it's one that has demonstrated how
22 quickly we can move out.

23 The vaccine guidance and vaccine shots in
24 arms has given us a kind of a ray of hope here.
25 Spring is coming, vaccines are getting in arms

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1 and people are feeling better, but the economy
2 is still struggling and the guidance that seems
3 to be coming is not perhaps consistent with
4 what we're seeing on the ground or this is what
5 Alaskans are sharing with me.

6 We have a significant tourist industry.
7 We welcome people to come up. We want them to
8 be safe. We're going to encourage all of the
9 continuing protocols, but we've been struggling
10 trying to get the economy back on track when
11 60 percent of your tourists come to the State
12 of Alaska come by cruise ship, we've got a
13 conditional no sale order or conditional sale
14 order in place, effectively a no sale order.

15 Dr. Walensky, we've had an opportunity to
16 speak with folks on your team. Alaskans aren't
17 pushing to say don't send people our way if
18 it's not safe; don't use this if it's not safe,
19 but what they are asking for is some kind of
20 guidance in terms of timeline. It's the
21 timeline so you can know to plan.

22 Do we go ahead and -- the hundreds of
23 small businesses that are reliant on these
24 tourists coming up, do they open up or do they
25 acknowledge this is going to be the second

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1 season in a year where they will have nothing
2 and effectively nowhere to shudder their
3 operations now.

4 So when we're talking about health
5 impacts, we all want to make sure we're
6 following the guidance and science and all that
7 comes with that, but there's also this
8 recognition of the economic impact. Certainty
9 is helpful. We haven't had much certainty with
10 this virus and it's been challenging.

11 Can you give me any kind of guidance to
12 give Alaskans in terms of what we might be able
13 to expect with where this guidance is in the
14 process. When you say "later", does that mean
15 at the end of 2021? Does it mean in three
16 months? Does it mean in one month? What kind
17 of guidance can you provide when it comes to
18 the CDC's order as it relates to the
19 conditional sale order?

20 DR. WALENSKY: Thank you for that
21 question. Yeah, so first of all, I am -- I
22 understand the economic impact of the no sale
23 or -- the no sale, the conditional sale and the
24 travel. So we don't take that lightly.

25 We have provided technical assistance on

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1 the conditional sale where we've provided a
2 four phase strategy for how we could get sale
3 open. We are in Phase 1 of that moving towards
4 Phase 2.

5 This is an inter-agency decision. It is
6 not a decision solely up to the CDC, so this
7 would be -- I would be remiss if I was able to
8 do that by myself because the decision is not
9 solely up to us.

10 SENATOR MURKOWSKI: The second phase,
11 going to that second phase, can you give me
12 some indicator in terms of a timeline there?

13 DR. WALENSKY: I can't simply because I
14 don't believe it's solely in our jurisdiction
15 to address, it's not necessarily a CDC --

16 SENATOR MURKOWSKI: So who else is -- is
17 part of the decision-making process then beyond
18 CDC?

19 DR. WALENSKY: I believe Department of
20 Transportation, OMB, there are numerous others
21 that are making these decisions.

22 SENATOR MURKOWSKI: I want to follow up
23 with you. I know we have an opportunity for
24 that later and I'll look forward to that, but
25 again, you need to -- CDC's role is to work

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1 through the health safety, we understand and we
2 respect that, but just trying to gain some
3 sense as to timing.

4 * * * * *

5 (Video transcription concluded.)

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CERTIFICATE OF REPORTER

STATE OF FLORIDA
COUNTY OF LEE

I, AMORY RANCK, Florida Professional Reporter, do hereby certify that I was authorized to and did stenographically transcribe the foregoing audio recording and that the transcript is a true record of my stenographic notes.

Dated this 13th day of March, 2021. 

AMORY RANCK, FPR

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